

Allen Amsler, Chairman Ann B. Kirol, DDS, Vice Chair L. Clarence Batts, Jr., Secretary

R. Kenyon Wells Charles M. Joye II, P.E. David W. Gillespie, MD

South Carolina Board of Health and Environmental Control November 9, 2017

Call to Order – 10:00 a.m., Board Room (#3420) South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C.

- 1. Minutes of the October 12, 2017 meeting
- 2. Administrative Orders, Consent Orders and Sanction Letters issued by Health Regulation
- 3. Administrative Orders, Consent Orders and Consent Agreements issued by Environmental Affairs
- 4. Request for a nine month extension by the Board of Certificate of Need (CON) SC-15-26 issued to Medical University Hospital Authority d/b/a Medical University of South Carolina (MUSC) for renovation of existing facility for the addition of fifty-two (52) acute hospital beds for a total of six hundred fifty-six (656) acute hospital beds, the purchase of a Siemens Artis Q Biplane, and the renovation of the existing inpatient pharmacy
- 5. Notice of Proposed Regulation amending Regulation 61-78, Standards for Licensing Hospices
- 6. Placement of ortho-Fluorofentanyl, Tetrahydrofuranyl Fentanyl, and Methoxyacetyl Fentanyl into Schedule I for S.C. Controlled Substances
- 7. Placement of the synthetic cannabinoid, methyl 2-(1-(4-fluorobenzyl)-1 Hindazole-3carboxamido)-3-methylbutanoate [FUB-AMB, MMBFUBINACA, AMB-FUBINACA], and its optical, positional, and geometric isomers, salts, and salts of isomers into schedule I
- 8. Agency Affairs

Executive Session (if needed)

Adjournment

Note: The next scheduled meeting is December 7.

SUMMARY SHEET SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

November 9, 2017

- () ACTION/DECISION
- (X) INFORMATION
- I. TITLE: Health Regulation Administrative and Consent Orders.
- II. SUBJECT: Health Regulation Administrative Orders, Consent Orders, and Emergency Suspension Orders for the period of September 1, 2017, through September 30, 2017.
- III. FACTS: For the period of September 1, 2017, through September 30, 2017, Health Regulation reports four (4) Consent Orders, three (3) Emergency Suspension Orders, and one (1) License Suspension with a total of five thousand eight hundred fifty dollars (\$5,850) in assessed monetary penalties.

Health Regulation Bureau	Health Care Facility, Provider, or Equipment	Administrative Orders	Consent Orders	Emergency Suspension Orders	License Suspensions	Assessed Penalties
Health Facilities Licensing	Community Residential Care Facility	0	1	0	0	\$4,150
	Adult Day Care	0	1	0	0	\$400
Radiological Health	Medical Facility	0	2	0	0	\$1,300
EMS & Trauma	Pararnedic	0	0	1	0	\$0
	l l		0	2	0	\$0
	Ambulance Services Provider	0	0	0	1	\$0
TOTAL		0	4	3	1	\$5,850

Approved By:

Shelly Bezanson Kelly
Director of Health Regulation

HEALTH REGULATION ENFORCEMENT REPORT SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

November 9, 2017

Bureau of Health Facilities Licensing

Facility Type	Total#of Beds or Participants	Total # of Licensed Facilities in South Carolina
Community Residential Care Facility	19,144	479

1. Heath Springs Residential Care Facility (CRCF) – Heath Springs, SC

<u>Investigation</u>: The Department visited Heath Springs Residential Care Facility ("Heath Springs") on March 25, 2016, to conduct a general inspection, and December 29, 2016, to conduct a complaint investigation.

<u>Violations</u>: Based upon the inspections, the Department cited Heath Springs for five (5) violations of Regulation 61-84, <u>Standards for Licensing Community Residential Care Facilities</u>. Specifically, Heath Springs was cited one (1) time for violating Section 401, for failing to document in a resident's record the general well-being of the resident in accordance with facility policies and procedures; one (1) time for violating Section 504.A, for failing to ensure a staff member received required training prior to resident contact; one (1) time for violating Section 601.D, for failing to submit to the Department within five (5) days a written report of the facility's investigation of an incident; one (1) time for violating Section 801.B, by admitting and retaining a person inappropriate for placement in a CRCF; and one (1) time for violating Section 1101.A, for failing to ensure physical examinations of two (2) residents were completed within thirty (30) days prior to admission to the facility.

Enforcement Action: Pursuant to the Consent Order executed September 28, 2017, the Department assessed a four thousand one hundred fifty dollar (\$4,150) monetary penalty against Heath Springs, due within thirty (30) days of execution of the Consent Order. Additionally, Heath Springs agreed to correct the violations that initiated this enforcement action and ensure that all violations of R.61-84 are not repeated. Finally, Heath Springs agreed to schedule and attend a compliance assistance meeting with Department representatives within forty-five (45) days of execution of the Consent Order. The Department received Heath Springs' assessed monetary penalty on September 12, 2017.

Prior Sanctions: None.

Facility Type	Total # of Participants	Total # of Licensed Facilities in South Carolina	
Day Care Facilities for Adults	4,618	75	

2. Tucker's Adult Health Day Care (ADC) - Walterboro, SC

<u>Investigation</u>: The Department visited Tucker's Adult Health Day Care ("Tucker's") on January 10, 2017, to conduct a routine inspection.

<u>Violations:</u> Based upon the inspections, the Department cited Tucker's for four (4) violations of Regulation 61-75, <u>Standards for Licensing Day Care Facilities for Adults</u>. Specifically, Tucker's was

cited two (2) times for violating Section 202.D, by failing to submit a Plan of Correction ("POC") for violations cited as a result of the Department's routine inspection; one (1) time for violating Section 404.F.1, for failing to have documentation of training on fire safety measures for staff members available for review; and one (1) time for violating Section 404.G, for failing to have documentation of annual performance evaluations for staff members available for review.

Enforcement Action: Pursuant to the Consent Order executed September 29, 2017, the Department assessed a four hundred dollar (\$400) monetary penalty against Tucker's. The Consent Order required Tucker's to pay one hundred dollars (\$100) of the assessed penalty within thirty (30) days of execution of the Consent Order. The remainder of the assessed penalty will be held in abeyance pending Tucker's submitting acceptable POCs to the Department within fifteen (15) days of execution of the Consent Order. Additionally, Tucker's agreed to correct the violations that initiated this enforcement action and ensure that all violations of R.61-84 are not repeated. The Department received the assessed monetary penalty from Tucker's on August 31, 2017.

Prior Sanctions: None.

Bureau of Radiological Health

Facility Type	Total # of Registered Facilities in South Carolina		
Medical Facilities	821		

3. Premier Clinics, PA - Rock Hill (Medical Facility) - Rock Hill, SC

<u>Investigation</u>: The Department visited Premier Clinics, PA – Rock Hill ("Registrant") on October 14, 2016, to conduct a routine inspection.

<u>Violations:</u> Based upon the inspection, the Department cited Registrant for two (2) violations of Regulation 61-64, <u>X-Rays (Title B)</u>. Specifically, Registrant was cited one (1) time for violating RHB 3.12.3.1.4, for failing to ensure that personnel monitoring devices are returned within forty-five (45) days of the end of the monitoring period; and one (1) time for violating RHB 4.2.16.1, for failing to conduct equipment performance tests on its x-ray unit in 2014 and 2015, and inadequate equipment performance testing in 2016. Both violations are repeat violations.

Enforcement Action: Pursuant to the Consent Order executed September 29, 2017, Registrant agreed to a four hundred dollar (\$400) civil penalty, due within thirty (30) days of execution of the Consent Order. Additionally, Registrant agreed to a twenty-four (24) month period of substantial compliance with the terms of the Consent Order and R.61-64. Finally, Registrant agreed to ensure that all violations of R.61-64 are not repeated. The Department received the civil penalty from Registrant on September 27, 2017.

Prior Sanctions: None.

4. Premier Clinics, PA - Chester (Medical Facility) - Chester, SC

<u>Investigation</u>: The Department visited Premier Clinics, PA – Chester ("Registrant") on July 27, 2016, to conduct a routine inspection.

<u>Violations:</u> Based upon the inspection, the Department cited Registrant for four (4) violations of Regulation 61-64, <u>X-Rays (Title B)</u>. Specifically, Registrant was cited one (1) time for violating RHB

3.22.1, for failing to produce records of individual monitoring; one (1) time for violating RHB 4.2.2, for failing to produce a valid South Carolina Radiation Quality Standards Association for an x-ray unit operator; one (1) time for violating RHB 4.2.2.7, for failing to produce documentation of facility specific operator training for machine operators; and one (1) time for violating RHB 4.2.16.1, for failing to conduct required equipment performance tests on its x-ray unit. All violations are repeat violations.

Enforcement Action: Pursuant to the Consent Order executed September 29, 2017, Registrant agreed to a nine hundred dollar (\$900) civil penalty, due within thirty (30) days of execution of the Consent Order. Additionally, Registrant agreed to a twenty-four (24) month period of substantial compliance with the terms of the Consent Order and R.61-64. Finally, Registrant agreed to ensure that all violations of R.61-64 are not repeated. The Department received the civil penalty from Registrant on September 27, 2017.

Prior Sanctions: None.

Bureau of EMS & Trauma

EMS Provider Type	Total # of Providers in South Carolina		
EMT	7,223		
Advanced EMT	490		
Paramedic	4,040		
Athletic Trainers	1,029		
Ambulance Services Provider	281		
First Responder Services Provider	2		

5. Joshua W. Vaughn (Paramedic)

<u>Investigation:</u> On September 18, 2017, the Department was notified of Mr. Vaughn's arrest in Ware Shoals, South Carolina. Upon notification, the Department initiated an investigation into the matter. The Department discovered that Mr. Vaughn was arrested on September 13, 2017, and charged with disseminating obscene material to a minor.

<u>Violations:</u> The charge against Mr. Vaughn, specifically, disseminating obscene material to a minor, is a felony involving moral turpitude and gross immorality. The Department found that Mr. Vaughn's arrest demonstrated a capacity for inappropriate and criminal behavior towards individuals placed within his trust. The Department determines that a clear and present danger would exist to the public health, safety, and welfare if Mr. Vaughn's Paramedic certificate was not immediately suspended pending further investigation.

<u>Enforcement Action:</u> Mr. Vaughn's Paramedic certificate was immediately suspended on an emergency basis pursuant to the Emergency Suspension Order executed September 20, 2017. The Department will continue to monitor Mr. Vaughn's criminal matters.

Prior Sanctions: None.

6. Jaron O. Livingstor (EMT)

<u>Investigation:</u> On August 16, 2017, the Department was notified of Mr. Livingston's arrest in Oconee County, South Carolina. Upon notification, the Department initiated an investigation into the matter. The Department discovered that Mr. Livingston was arrested on August 3, 2017, and charged with two (2) counts of second degree criminal sexual conduct with a minor.

<u>Violations:</u> The charges against Mr. Livingston, specifically, two (2) counts of second degree criminal sexual conduct with a minor, is a felony involving moral turpitude and gross immorality. The Department found that Mr. Livingston's arrest demonstrated a capacity for inappropriate and criminal behavior towards individuals placed within his trust. The Department determines that a clear and present danger would exist to the public health, safety, and welfare if Mr. Livingston's EMT certificate was not immediately suspended pending further investigation.

<u>Enforcement Action:</u> Mr. Livingston's EMT certificate was immediately suspended on an emergency basis pursuant to the Emergency Suspension Order executed September 20, 2017. The Department will continue to monitor Mr. Livingston's criminal matters.

Prior Sanctions: None.

7. Springlake Medical Transport, LLC (Ambulance Services Provider)

Summary: On May 5, 2017, Springlake Medical Transport, LLC ("Springlake") and the Department executed a Consent Order resulting from several regulatory violations involving Springlake's failure to submit electronic patient care reports ("ePCRs") within seventy-two (72) hours of the completion of calls. Pursuant to the Consent Order, Springlake agreed to the assessment of a one thousand five hundred dollar (\$1,500) monetary penalty. Additionally, pursuant to the Consent Order, Springlake agreed to a six (6) month suspension if it violated the Consent Order, the EMS Act, or Regulation 61-7 during the six (6) months following execution.

<u>Violations:</u> Springlake violated Section 1301.C of R.61-7 by failing to submit seventy-eight (78) ePCRs within seventy-two (72) hours of the completion of various calls from May 6, 2017, to August 8, 2017.

Enforcement Action: Springlake's EMS provider license was suspended for two (2) months upon delivery of a certified letter on September 20, 2017. Springlake may not perform the functions associated with its provider license until it has complied with the statutory requirements and other conditions imposed by the Department

<u>Prior Sanctions:</u> On May 5, 2017, the Department and Springlake executed a Consent Order for several regulatory violations involving Springlake's failure to submit ePCRs within the required timeframe. The Consent Order assessed a one thousand five hundred dollar (\$1,500) monetary penalty against Springlake.

8. Nicholas J. V. Jimno (EMT)

<u>Investigation</u>: On September 8, 2017, the Department was notified of Mr. Jimno's arrest in Charleston County, South Carolina. Upon notification, the Department initiated an investigation into the matter. The Department discovered that Mr. Jimno was arrested on August 23, 2017, and charged with three (3) counts of criminal solicitation of a minor, and one (1) count of disseminating obscene material to a person under 18 years of age.

<u>Violations</u>: The charges against Mr. Jimno, specifically, three (3) counts of criminal solicitation of a minor, and one (1) count of disseminating obscene material to a person under 18 years of age, are felonies against morality and decency and involve moral turpitude and gross immorality. The Department found that Mr. Jimno's arrest demonstrated a capacity for inappropriate and criminal behavior towards

individuals placed within his trust. The Department determines that a clear and present danger would exist to the public health, safety, and welfare if Mr. Jimno's EMT certificate was not immediately suspended pending further investigation.

<u>Enforcement Action:</u> Mr. Jimno's Paramedic certificate was immediately suspended on an emergency basis pursuant to the Emergency Suspension Order executed September 8, 2017. The Department will continue to monitor Mr. Jimno's criminal matters.

Prior Sanctions: None.

SUMMARY SHEET BOARD OF HEALTH AND ENVIRONMENTAL CONTROL November 9, 2017

	ACTION/DECISION		
X	INFORMATION		

- **1. TITLE:** Administrative and Consent Orders issued by Environmental Affairs.
- **2. SUBJECT:** Administrative and Consent Orders issued by Environmental Quality Control (EQC) and Ocean and Coastal Resource Management (OCRM) during the period August 1, 2017 August 31, 2017.
- **3. FACTS:** For the period of September 1, 2017 through September 30, 2017, Environmental Affairs issued ninety-four (94) Consent Orders with total assessed civil penalties in the amount of \$121,550.00. Five (5) Administrative Orders were issued during the reporting period with total assessed civil penalties in the amount of \$59,500.00. Also, three (3) Consent Agreements were issued during the reporting period.

Bureau and Program Area	Administrative Orders	Assessed Penalties	Consent Agreements	Consent Orders	Assessed Penalties
Land and Waste Management					
UST Program	0	0	0	6	\$5,600.00
Aboveground Tanks	0	0	0	0	0
Solid Waste	2	\$56,500.00	0	2	\$3,500.00
Hazardous Waste	0	0	0	1	\$8,000.00
Infectious Waste	0	0	0	2	\$19,500.00
Mining	0	0	0	1	\$1,000.00
SUBTOTAL	2	\$56,500.00	0	12	\$37,600.00
Water					
Recreational Water	1	\$1,000.00	0	11	\$8,500.00
Drinking Water	0	0	0	2	\$1,000.00
Water Pollution	0	0	0	1	\$2,500.00
Dam Safety	0	0	3	0	0
SUBTOTAL	1	\$1,000.00	3	14	\$12,000.00
Air Quality					
SUBTOTAL	0	0	0	2	\$9,000.00
Environmental Health Services					
Food Safety	2	\$2,000.00	0	66	\$62,950.00
Onsite Wastewater	0	0	0	0	0
SUBTOTAL	2	\$2,000.00	0	66	\$62,950.00
OCRM					
SUBTOTAL	0	0	0	0	0
TOTAL	5	\$59,500.00	3	94	\$121,550.00

Submitted by:

Myra C. Reece

Director of Environmental Affairs

Ohna V. Ruce

ENVIRONMENTAL AFFAIRS ENFORCEMENT REPORT BOARD OF HEALTH AND ENVIRONMENTAL CONTROL November 9, 2017

BUREAU OF LAND AND WASTE MANAGEMENT

Underground Storage Tank Enforcement

1) Order Type and Number: Consent Order 17-0166-UST

Order Date: September 12, 2017

Individual/Entity: Aaniya LLC

Facility: Woodruff Truck Plaza
Location: 4225 Walnut Grove Road

Roebuck, SC 29376

Mailing Address: Same

<u>County</u>: Spartanburg

*Previous Orders: None Permit/ID Number: 08226

<u>Violations Cited</u>: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 *et seq.* (2002 and Supp. 2014); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann. Regs. 61-92.280.20(c)(1)(ii) (2012).

<u>Summary</u>: Aaniya LLC (Individual/Entity), located in Roebuck, South Carolina, owns and operates underground storage tanks. On June 9, 2017, the Department conducted a routine inspection and issued a Notice of Alleged Violation because there was no drop tube shutoff valve present on the regular unleaded tank #2. On June 28, 2017, a permanent cap was installed on the fill of the regular unleaded tank #2. The Individual/Entity has violated the State Underground Petroleum Environmental Response Bank Act and the South Carolina Underground Storage Tank Control Regulation, as follows: failed to maintain overfill prevention equipment.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of one thousand dollars (\$1,000.00).

2) <u>Order Type and Number</u>: Consent Order 17-0168-UST

Order Date: September 12, 2017

<u>Individual/Entity</u>: **Anil Patel d.b.a. Shree Saintram, Inc.**

<u>Facility</u>: Harsh Mart

<u>Location</u>: 498 East Blackstock Road

Spartanburg, SC 29307

Mailing Address: Same

<u>County</u>: Spartanburg

<u>Previous Orders:</u> None <u>Permit/ID Number:</u> 10586

<u>Violations Cited</u>: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 *et seq.* (2002 and Supp. 2014); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann. Regs. 61-92.280.20(c)(1)(ii) (2012).

<u>Summary</u>: Anil Patel d.b.a. Shree Saintram, Inc. (Individual/Entity), located in Spartanburg, South Carolina, owns and operates underground storage tanks. On June 9, 2017, the Department conducted a routine inspection and issued a Notice of Alleged Violation because there was no drop tube shutoff valve present on the premium tank. On June 26, 2017, the Department received a copy of an invoice from Carolina Registers as proof that a drop tube shutoff valve had been installed on the premium tank. The Individual/Entity has violated the State Underground Petroleum Environmental Response Bank Act and the South Carolina Underground Storage Tank Control Regulation, as follows: failed to maintain overfill prevention equipment.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of one thousand dollars **(\$1,000.00)**.

3) Order Type and Number: Consent Order 17-0197-UST

Order Date:September 12, 2017Individual/Entity:Michael LanceFacility:Lances Mini MartLocation:10088 Highway 707

Myrtle Beach, SC 29575

Mailing Address:SameCounty:HorryPrevious Orders:NonePermit/ID Number:10771

Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 et seq. (2002 and Supp. 2014), and South Carolina Underground Storage Tank Control Regulation (Regulation), 7 S.C. Code Ann. Regs. 61-92.280.93(a) and 280.110(c) (2012).

<u>Summary</u>: Michael Lance (Individual/Entity), located in Myrtle Beach, South Carolina, owns and operates underground storage tanks. The Department conducted a file review on May 17, 2017, and issued a Notice of Alleged Violation because there was no current financial responsibility documentation on file with the Department. The Individual/Entity has violated the State Underground Petroleum Environmental Response Bank Act and the South Carolina Underground Storage Tank Control Regulation, as follows: failed to demonstrate financial responsibility for an UST system; and failed to submit evidence of financial assurance to the Department upon request.

<u>Action</u>: The Individual/Entity is required to: submit a completed Certificate of Financial Responsibility and proof of financial documentation; and pay a civil penalty in the amount of one thousand, two hundred dollars (\$1,200.00).

4) <u>Order Type and Number</u>: Consent Order 16-0426-UST

Order Date: September 26, 2017

Individual/Entity: Anderson Oil Company of Florence

Facility: Bull Mart 3

Location: 3140 East highway 501

Aynor, SC

Mailing Address: 3366 West Palmetto Street

Florence, SC 29501

County:HorryPrevious Orders:NonePermit/ID Number:15032

<u>Violations Cited</u>: South Carolina Underground Storage Tank Control Regulation (2012), and, State Underground Petroleum Environmental

Response Bank Act of 1988 (2002 and Supp. 2014).

<u>Summary</u>: Anderson Oil Company of Florence (Individual/Entity) formerly owned and operated a 4,000-gallon kerosene underground storage tank (UST) in Horry County, South Carolina. The UST was abandoned by removal from the ground in June 2016. A file review conducted on October 13, 2016. The Individual/Entity has violated the South Carolina Underground Storage Tank Control Regulation and the State Underground Petroleum Environmental Response Bank Act as follows: failed to submit a UST Closure and Assessment report after permanent closure of a UST system.

Action: The Individual/Entity is required to: submit a UST Closure and Assessment report; and pay a civil penalty in the amount of four hundred ninety dollars (\$490.00).

5) Order Type and Number: Consent Order 17-0182-UST

Order Date: September 26, 2017
Individual/Entity: Mixson Oil Co., Inc.
Facility: Mixson Oil Co., Inc.

<u>Location</u>: 4301 Allendale Fairfax Highway

Allendale, SC 29810

Mailing Address: P.O. Box 637

Allendale, SC 29810

County:AllendalePrevious Orders:NonePermit/ID Number:00305

<u>Violations Cited</u>: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 *et seq.* (2002 and Supp. 2014); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann. Regs. 61-92.280.44(a) (2017).

<u>Summary</u>: Mixson Oil Co., Inc. (Individual/Entity), located in Allendale, South Carolina, owns and operates underground storage tanks. On June 20, 2017, the Department conducted a routine inspection and issued a Notice of Alleged Violation because there was no line leak detector installed on the regular unleaded tank #3. On July 5, 2017, the Department received proof that a mechanical line leak detector had been installed on the regular unleaded tank #3. The Individual/Entity has violated the State Underground Petroleum Environmental Response Bank Act and the South Carolina Underground Storage Tank Control Regulation, as follows: failed to install a leak detector on a pressurized line to monitor for a 3.0 GPH leak.

<u>Action</u>: The Individual/Entity is required to: pay a civil penalty in the amount of one thousand dollars **(\$1,000.00)**.

6) <u>Order Type and Number</u>: Consent Order 17-0214-UST

Order Date: September 27, 2017

<u>Individual/Entity</u>: **Empire Petroleum Properties, LLC**

<u>Facility</u>: Curgin's Corner, LLC

<u>Location</u>: 3446 Jefferson Davis Highway

Greenville, SC

Mailing Address: 8350 North Central Expressway, M2175

Dallas, Texas 75206

<u>County</u>: Greenville

<u>Previous Orders</u>: None

<u>Permit/ID Number</u>: 19004

<u>Violations Cited</u>: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 *et seq.* (2002 and Supp. 2016); and South Carolina Underground Storage Tank Control

Regulation, 7 S.C. Code Ann. Regs. 61-92.280.40(a)(1) and (2) (2017).

<u>Summary</u>: Empire Petroleum Properties, LLC (Individual/Entity) owns and operates underground storage tanks (USTs) located in Greenville, South Carolina. On June 30, 2017, the Department conducted a routine inspection. The Individual/Entity has violated the State Underground Petroleum Environmental Response Bank Act and the South Carolina Underground Storage Tank Control Regulation as follows: failed to provide release detection from any portion of the tank and the connected underground piping; and failed to maintain release detection on underground piping in accordance with manufacturer's instructions.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of one thousand dollars (\$1,000.00).

Solid Waste Enforcement

7) <u>Order Type and Number</u>: Administrative Order 17-20-SW

Order Date: August 23, 2017

Individual/Entity: VIVA Recycling of South Carolina, LLC

Facility: VIVA Moncks Corner Location: 111 Old Depot Road

Moncks Corner, SC

Mailing Address: P.O. Box 12879

Charleston, SC 29422-2879

<u>County</u>: Berkeley

<u>Previous Orders</u>: Settlement Agreement and Consent

Order of Dismissal 16-ALJ-07-0062-CC (\$5,000.00 plus a stipulated penalty of

\$47,500.00)

Consent Order 15-05-SW (\$12,000.00)

Permit/ID Number: 082728-5201

<u>Violations Cited</u>: South Carolina Solid Waste Policy and Management Act of 1991 (Act) (2002) and Solid Waste Management: Waste Tire Regulation 61-107.3 (2015)

Summary: VIVA Recycling of South Carolina, LLC (Individual/Entity), located in Moncks Corner, South Carolina, is a permitted waste tire collection and processing facility that produces tire derived fuel and other products from waste tires. The Department conducted four (4) inspections to determine compliance with the Settlement Agreement and Consent Order of Dismissal (Court Order) from April 2017 to June 2017. The Court Order was issued on April 17, 2017. Based upon these inspections, the Individual/Entity has violated the Settlement Agreement and Consent Order of Dismissal, the Permit, and Regulation 61-107.3 as follows: failed to pay the civil penalty (\$5,000.00) and the stipulated penalty (\$47,500.00) under the Court Order; failed to provide temporary financial assurance in the amount of \$215,000.00; and, failed to implement the remediation plan under the Court Order.

Action: Administrative Order 17-20-SW revokes Permit 082728-5201. The Individual/Entity is required to: cease all waste tire collection and processing at the Facility; post closure signs at the Facility; submit a Closure Plan to the Department for the removal and proper disposal or recycling or sale of all waste tires, partial waste tires, shreds, used tires, tire delivered fuel, side walls, and solid waste at the Facility, within six (6) months of the Department's approval of the plan; obtain a third-party company to provide mosquito control and start control measures; pay the civil penalty in the amount of fifty-two thousand, five hundred dollars (\$52,500.00) under Settlement Agreement and Consent Order of Dismissal (Docket No. 16-ALJ-07-0062-CC); and, pay a suspended penalty in the amount of one million, six hundred forty-seven thousand, three hundred seventy-two dollars (\$1,647,372.00) should any requirement of the Order not be met.

8) <u>Order Type and Number</u>: Administrative Order 17-21-SW

Order Date: September 12, 2017

Individual/Entity: VIVA Recycling Upstate, LLC

Facility: VIVA Anderson

Location: 3520 Abbeville Highway

Anderson, SC

Mailing Address: P.O. Box 12879

Charleston, SC 29422-2879

<u>County</u>: Anderson

Previous Orders: Consent Order 17-01-SW (\$76,125.00)

Settlement Agreement and Consent Order of Dismissal 16-ALJ-07-0063-CC

(\$10,000.00)

Permit/ID Number: 042417-5201

<u>Violations Cited</u>: South Carolina Solid Waste Policy and Management Act of 1991 (Act) (2002) and Solid Waste Management: Waste Tire Regulation 61-107.3 (2015)

Summary: VIVA Recycling Upstate, LLC (Individual/Entity), located in Anderson, South Carolina, is a permitted waste tire collection and processing facility that produces tire derived fuel and other products from waste tires. The Department conducted inspections to determine compliance with Consent Order 17-01-SW on April 10, 2017, April 19, 2017; April 26, 2017; May 3, 2017; May 8, 2017; May 12, 2017; June 9, 2017; June 19, 2017; June 30, 2017; July 3, 2017; and August 3, 2017. Based upon these inspections, the Individual/Entity has violated Consent Order 17-01-SW, as follows: failed to pay a stipulated penalty in the amount of four thousand dollars (\$4,000.00) under the Court Order; failed to manage waste tires as defined in the Permit; failed to adhere to the phased close out plan and timelines for removal of the waste tire wall; and failed to notify the Department that it removed permitted shredders from the facility.

Action: The Administrative Order revokes the permit. The Individual/Entity is required to: cease all waste tire collection and processing at the facility, post closure signs at the facility, submit a Closure Plan to the Department for the removal and proper disposal or recycling or sale of all waste tires, partial waste tires, shreds, tire wall materials, used tires, tire delivered fuel, side walls, and solid waste at the Facility within six (6) months of the Department's approval of the plan, obtain a third-party company to provide mosquito control and start control measures, and pay a civil penalty in the amount of four thousand dollars (\$4,000.00) as issued under Consent Order 17-01-SW; and, pay a suspended penalty in the amount of fifty-two thousand, five hundred dollars (\$52,500.00) should any requirement of the Order not be met.

9) Order Type and Number: Consent Order 17-02-SW

Order Date: September 8, 2017

Individual/Entity: General Equipment & Supply Company, Inc. Facility: General Equipment & Supply Company, Inc.

<u>Location</u>: 3423 Fork Shoals Road

Simpsonville, SC 29680

Mailing Address:SameCounty:GreenvillePrevious Orders:NonePermit/ID Number:N/A

Violations Cited: The South Carolina Solid Waste Policy and Management Act of 1991 S.C. Code Ann. §44-96-100 *et seq.* (2002 and Supp. 2015); The South Carolina Solid Waste Management: Used Oil Regulations, 8 S.C. Code Ann. Regs. 61-107.279.22 (c)(1), R. 61-107.279.22 (d) (2016).

<u>Summary</u>: General Equipment & Supply Company, Inc. (Individual/Entity) operates a facility in Simpsonville, South Carolina. On January 26, 2016, the Department conducted an inspection of the facility in response to a complaint received by the EPA. The Individual/Entity violated the South Carolina Solid Waste Management: Used Oil Regulations as follows: failed to mark containers and above ground tanks used to store used oil labeled or marked clearly with the words "Used Oil;" and, failed to perform the following steps upon detection of a release of used oil to the environment: stop the release; contain the released used oil; clean up and manage properly the released used oil and other materials; and, if necessary to prevent future releases, repair or replace any leaking used oil storage containers or tanks prior to returning them to service.

Action: The Individual/Entity has agreed to pay a civil penalty in the amount of three thousand dollars (\$3,000.00).

10) <u>Order Type and Number</u>: Consent Order 17-19-SW

Order Date: September 20, 2017
Individual/Entity: Dennis Ray Cash
Facility: Dennis Ray Cash

<u>Location</u>: Lot 103 on Keowee Lakeshore Drive

Seneca, SC

Mailing Address: 1712 Keowee Lakeshore Drive

Seneca, SC 29672

County:OconeePrevious Orders:NonePermit/ID Number:N/A

<u>Violations Cited</u>: The South Carolina Solid Waste Policy and Management Act of 1991 §44-96-10; and the Solid Waste Management: Solid Waste

Landfills and Structural Fill, R.61-107.19. Part II(B)(1).

<u>Summary</u>: Dennis Ray Cash (Individual/Entity), owns property located at Lot 103 on Keowee Lakeshore Drive (Site), in Seneca, South Carolina. On February 9, 2017, the Department visited the Site in response to a complaint regarding the unauthorized disposal of Construction and Demolition (C&D) material (concrete, block and brick). The Individual/Entity has violated the South Carolina Solid Waste Management: Solid Waste Landfills and Structural Fill Regulation as follows: failed to receive written approval from the Department to operate under the Permit-by-rule for a specific site, prior to engaging in structural fill activity.

Action: The Individual/Entity is required to establish required side slopes (3:1) in the current fill area; apply a minimum two (2) foot thick final earthen cover with at least a 1% but not greater than 4% surface slope on the top of the structural fill that is already to final elevation and grade, ensuring that the side slope cover shall not exceed three horizontal feet to one vertical foot; seed the finished surface of the filled area with native grasses or other suitable ground cover to establish and maintain into the second growing season a 75% or greater permanent vegetative cover with no substantial bare spots; implement stormwater controls to manage runoff along the toe of the ravine; submit proof that a notation had been made with the appropriate Register of Deeds in the record of ownership of property; and, pay

a civil penalty in the amount of five hundred dollars (\$500.00).

Hazardous Waste Enforcement

11) <u>Order Type and Number</u>: Consent Order 17-22-HW

Order Date: September 20, 2017

Individual/Entity:Palmetto Health TuomeyFacility:Palmetto Health TuomeyLocation:129 North Washington Street

Sumter, SC 29150

Mailing Address:SameCounty:SumterPrevious Orders:N/A

Permit/ID Number: SCD 982 130 338

<u>Violations Cited</u>: The South Carolina Hazardous Waste Management Act, S.C. Code Ann. §44-56-10 *et seq.* (2002 and Supp. 2016), and the South Carolina Hazardous Waste Management Regulation, 6 and 7 S.C. Code Ann.

Regs. 61-79 (2012 and Supp. 2016).

<u>Summary</u>: Palmetto Health Tuomey (Individual/Entity) provides healthcare at its facility located at 129 North Washington Street, in Sumter, South Carolina. The Department conducted an inspection on May 18, 2017. The Individual/Entity has violated the Hazardous Waste Management Regulations as follows: failed to ensure while waste is being accumulated onsite, each container is labeled or marked clearly with the EPA Hazardous Waste Number(s) and the words: "Hazardous Waste – federal laws prohibit improper disposal; failed to prepare manifests according to the instructions included in the Appendix to 262 – Manifest Forms; and, failed to file a revised or new Notification Form with the Department when a new hazardous waste was produced.

Action: The Individual/Entity is required to: submit to the Department, an updated DHEC Form 2701 to include all the hazardous wastes generated at the facility; submit a written procedure/protocol for managing and tracking monthly generations for pharmaceutical P-listed, acute hazardous waste at the facility; and, pay a civil penalty in the amount of eight thousand dollars (\$8,000.00).

Infectious Waste Enforcement

12) <u>Order Type and Number</u>: Consent Order 17-25-IW <u>Order Date</u>: September 14, 2017

<u>Individual/Entity</u>: Wellness Family Medicine, Inc.

<u>Facility</u>: Wellness Family Medicine <u>Location</u>: 1241 Boiling Springs Highway

Spartanburg, South Carolina 29303

Mailing Address: Same

<u>County</u>: Spartanburg

<u>Previous Orders</u>: None

Permit/ID Number: SC42-1916G

Violations Cited: The South Carolina Infectious Waste Management Act, S.C. Code Ann. § 44-93-30 (2002 and Supp. 2016) (Act); and the South

Carolina Infectious Waste Management Regulation 61-105 (2012).

Summary: Wellness Family Medicine, Inc. (Individual/Entity) provides healthcare services at Wellness Family Medicine located at 1241 Boiling Spring Highway, in Spartanburg, South Carolina. The Facility has been registered in South Carolina as a generator of infectious waste since August 23, 2001. On March 27, 2017, the Department conducted an inspection of the Facility to investigate a compliant. The Individual/Entity has violated the South Carolina Infectious Waste Management Act and the South Carolina Infectious Waste Management Regulation as follows: failed to notify the Department, in writing and within thirty (30) days, when any changes occurred in the information required; failed to ensure a manifest was initiated when waste was transported offsite; failed to manage infectious waste in a manner which prevents exposure to the public or release to the environment; failed to treat infectious waste onsite or transport offsite for treatment at a permitted treatment facility; failed to obtain and record accurate weight of waste within 50 days of shipment; failed to meet the specific requirements of this section, as a small quantity generator, when transporting their own waste; failed to segregate infectious waste from solid waste as close to the point of generation as practical to avoid commingling of the waste; failed to label containers of infectious waste offered for transport offsite on the outside surfaces so that it was readily visible with the date the container was placed in storage or sent offsite, if not stored; failed to label containers of infectious waste offered for transport offsite on the outside surfaces so that it is readily visible with the Department issued number of the in-state generator; failed to label the storage area with the universal biohazard symbol sign; failed to meet at the minimum requirements of this section for each vehicle used to transport infectious waste; failed to maintain all records and manifest copies required by this regulation for a minimum of two (2) years; and, failed to maintain a record of the treatment for two (2) years afterward to include the date and type of treatment, amount of waste treated, and the individual operating the treatment.

Action: The Individual/Entity is required to: henceforth comply with the Act and Regulation 61-105; and, pay a civil penalty in the amount of thirteen thousand, five hundred dollars (\$13,500.00).

13) <u>Order Type and Number:</u> Consent Order 17-24-IW

Order Date: September 26, 2017

<u>Individual/Entity</u>: Allergy & Asthma Center <u>Facility</u>: Allergy & Asthma Center

<u>Locations</u>: 300 New River Parkway, Building 6, Suite 11

Hardeeville, SC; and 10B Marshellen Drive

Beaufort, SC

Mailing Address: 60 Main Street, Suite D

Hilton Head Island, SC 29926

<u>Counties</u>: Jasper & Beaufort

<u>Previous Orders</u>: None

Permit/ID Number: SC27-0061G and SC07-0429G

<u>Violations Cited</u>: The South Carolina Infectious Waste Management Act, S.C. Code Ann. § 44-93-30 (2002 and Supp. 2016) (Act); and the South

Carolina Infectious Waste Management Regulation 61-105 (2012).

Summary: Allergy & Asthma Center (Individual/Entity) provides healthcare services at the New River Office located in Hardeeville, South Carolina; and, at the Beaufort Office located in Beaufort, South Carolina. On September 20, 2016, and September 23, 2016, the Department conducted inspections at the New River Office. On September 20, 2016, Department staff attempted to conduct an inspection at the Beaufort Office. The Individual/Entity has violated the South Carolina Infectious Waste Management Act and the South Carolina Infectious Waste Management Regulation 61-105 as follows: failed to register with the Department, in writing, as an infectious waste generator; failed to ensure a manifest was initiated when waste was transported offsite; failed to label the storage area with the universal biohazard symbol sign; failed to maintain all records and manifest copies required by this regulation for a minimum of two (2) years; and, failed to maintain a record of the treatment for two (2) years afterward to include the date and type of treatment, amount of waste treated, and the individual operating the treatment.

Action: The Individual/Entity is required to henceforth comply with the Act and Regulation 61-105; and, pay a civil penalty in the amount of six thousand dollars (\$6,000.00).

Mining Enforcement

14) <u>Order Type and Number:</u> Consent Order 17-19-MSWM

Order Date: September 20, 2017

Individual/Entity: Okatie Construction, LLC

<u>Facility</u>: Magnolia Hill Mine <u>Location</u>: Lowcountry Drive

Ridgeland, SC

Mailing Address: 2789 Okatie Highway

Ridgeland, SC 29510

<u>County</u>: Jasper Previous Orders: None

Permit/ID Number: GP1-002105

<u>Violations Cited:</u> South Carolina Mining Act (2008 and Supp.

2015), and, South Carolina Mining Regulation (2012).

<u>Summary</u>: Okatie Construction, LLC (Individual/Entity) owns and operates a 5 acre mine under a General Permit in Jasper County, South Carolina. An inspection was conducted on January 27, 2017. The Individual/Entity has violated the South Carolina Mining Act, South Carolina Mining Regulation and the SC General Operating Permit as follows: conducted mining prior to obtaining an individual permit from the Department.

<u>Action</u>: The Individual/Entity is required to: cease and desist all mining activities until the individual permit is issued and effective; if the individual permit is not obtained, begin reclamation of the site; and pay a civil penalty in the amount of one thousand dollars (\$1,000.00).

BUREAU OF WATER

Recreational Water Enforcement

15) Order Type and Number: Administrative Order No. 17-111-RW

Order Date: August 24, 2017

<u>Individual/Entity</u>: **Lord Anson Arms Horizontal Property**

Regime

Facility: Lord Anson Arms

<u>Location</u>: 259 East Bay Street, Suite 6A

Charleston, SC 29401

Mailing Address:SameCounty:CharlestonPrevious Orders:NonePermit/ID Number:10-122-1

Violations Cited: S.C. Code Ann. Regs. 61-51(J) & S.C. Code Ann.

Regs. 61-51(C)(8)(b)

<u>Summary</u>: Lord Anson Arms Horizontal Property Regime (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On May 25, 2017, and July 11, 2017, the pool was inspected and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the gate did not self-close and latch; the chlorine and pH levels were not within the acceptable range of water quality standards; and the emergency notification device was not operational.

Action: The Individual/Entity is required to: submit a corrective action plan and schedule of implementation to address the deficiencies; and pay a civil penalty in the amount of one thousand dollars (\$1,000.00). The civil penalty has been paid.

16) <u>Order Type and Number:</u> Consent Order 17-115-RW

Order Date: September 5, 2017

<u>Individual/Entity</u>: **Hotel 230 Greystone Blvd. Opco, L.P.**<u>Facility</u>: Homewood Suites by Hilton Columbia

<u>Location</u>: 230 Greystone Boulevard

Columbia, SC 29210

Mailing Address:SameCounty:RichlandPrevious Orders:None

Permit/ID Number: 40-1022B & 40-1023D

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-51(J)

<u>Summary</u>: Hotel 230 Greystone Blvd. Opco, L.P. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool and spa. On May 24, 2017, and June 21, 2017, the pool and spa were inspected and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a handrail was missing a bolt cover; a ladder was missing bumpers; a ladder was missing a tread; the pool and spa walls were not clean; the deck and coping were chipped; the plaster on the pool floor was chipped; the pool furniture was not at least four feet from the edge of the pool; a skimmer was missing a weir; a skimmer lid was cracked; the chlorine and pH levels were not within the acceptable range of water quality standards; and the spa thermometer was not visible to the public.

Action: The Individual/Entity is required to: submit a corrective action plan and schedule of implementation to address the deficiencies; and pay a civil penalty in the amount of one thousand, three hundred sixty dollars (\$1,360.00).

17) <u>Order Type and Number</u>: Consent Order 17-116-RW

Order Date:September 6, 2017Individual/Entity:Francis X. WaltonFacility:1 Creative DriveLocation:1 Creative Drive

Columbia, SC 29210

<u>Mailing Address</u>: 159 Eagle Chase Court

Chapin, SC 29036

<u>County</u>: Richland <u>Previous Orders</u>: None Permit/ID Number: 40-079-1

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-51(J)(22)

<u>Summary</u>: Francis X. Walton (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On June 30, 2017, Department staff conducted an inspection of the pool and observed that the pool was closed to the public and was not being operated and maintained. Following the inspection, Department staff determined that the pool has been permanently closed. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: failure to fill in or remove the pool, which has been permanently closed for a period in excess of twenty-four consecutive months.

Action: The Individual/Entity is required to: make all required operational and maintenance upgrades to the pool, or fill in or remove the pool in accordance with an approved change order request form; and pay a **stipulated penalty** in the amount of three hundred forty dollars (**\$340.00**) should any requirement of the Order not be met.

18) <u>Order Type and Number:</u> Consent Order 17-117-RW

Order Date: September 8, 2017

<u>Individual/Entity</u>: **612 Devine Street Associates, LLC**<u>Facility</u>: The Apartments at Palmetto Compress

Location: 612 Devine Street

Columbia, SC 29201

Mailing Address:SameCounty:RichlandPrevious Orders:NonePermit/ID Number:40-1165B

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-51(J)

<u>Summary</u>: 612 Devine Street Associates, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On May 31, 2017, and July 12, 2017, the pool was inspected and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the gate did not self-close and latch; the chlorine and pH levels were not within the acceptable range of water quality standards; only one "Shallow Water – No Diving Allowed" sign was posted and the sign posted did not have the correct sized lettering; and only one "No Lifeguard On Duty – Swim At Your Own Risk" sign was posted and the sign posted did not have the correct sized lettering.

Action: The Individual/Entity is required to: submit a corrective action plan and schedule of implementation to address the deficiencies; and pay a civil penalty in the amount of six hundred eighty dollars (\$680.00).

19) Order Type and Number: Consent Order 17-118-RW

Order Date: September 14, 2017
Individual/Entity: CEV Upstate, LP

Facility: Campus Evolution Villages
Location: 101 Campus Suites Road

Spartanburg, SC 29303

Mailing Address: Same

<u>County</u>: Spartanburg

<u>Previous Orders</u>: 16-072-RW (\$680.00)

Permit/ID Number: 42-1060B

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-51(J)

Summary: CEV Upstate, LP (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On May 22, 2017, and August 2, 2017, the pool was inspected and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine and pH levels were not within the acceptable range of water quality standards; the facility address was not posted at the emergency notification device; the pool rules sign was not completely filled out; the bound and numbered log book was not maintained on a daily basis; and the cyanuric acid level was above the water quality standards acceptable limit.

<u>Action</u>: The Individual/Entity is required to: submit a corrective action plan and schedule of implementation to address the deficiencies; and pay a civil penalty in the amount of one thousand, three hundred sixty dollars **(\$1,360.00)**.

20) Order Type and Number: Consent Order 17-119-RW Order Date: September 18, 2017

Individual/Entity: Stratford Apartments 2016, LLC

<u>Facility</u>: Stratford Villas <u>Location</u>: 200 Eunice Drive

Greenville, SC 29617

Mailing Address: 11 Tori Court

Lakewood, NJ 08701

County:GreenvillePrevious Orders:NonePermit/ID Number:23-109-1

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-51(C)(11)

<u>Summary</u>: Stratford Apartments 2016, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On July 27, 2017, the pool was inspected and a violation was issued for failure to provide a drinking water fountain within fifty feet of the pool. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: there was no drinking water fountain within fifty feet of the pool.

Action: The Individual/Entity is required to: submit a corrective action plan and schedule of implementation to address the deficiency; and pay a civil penalty in the amount of three hundred forty dollars (\$340.00). The civil penalty has been paid.

21) Order Type and Number: Consent Order 17-120-RW

Order Date: September 19, 2017

Individual/Entity: Crestmont Apartments, LLC

Facility: Crestmont Apartments
Location: 34 Woodcross Drive

Columbia, SC 29212

Mailing Address:SameCounty:RichlandPrevious Orders:NonePermit/ID Number:40-1013B

Violations Cited: S.C. Code Ann. Regs. 61-51(J)

<u>Summary</u>: Crestmont Apartments, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On May 30, 2017, and July 11, 2017, the pool was inspected and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the pool walls were dirty with broken wall tiles next to the ladder; the pool floor was chipped; depth marker tiles were broken; the deck was chipped and the deck drains were broken; the pool equipment room was not locked; the gate did not self-close and latch; the life ring was not accessible and did not have a permanently attached rope; the current pool operator of record information was not posted to the public; the bound and numbered log book was not maintained on a daily basis and was not maintained a minimum of three times per week by the pool operator of record; and there were chlorine sticks in the skimmer baskets.

Action: The Individual/Entity is required to: submit a corrective action plan and schedule of implementation to address the deficiencies; and pay a civil penalty in the amount of six hundred eighty dollars (\$680.00).

Consent Order 17-121-RW 22) Order Type and Number:

> Order Date: September 20, 2017

Individual/Entity: Two Bridges Valley Creek, LLC

Facility: Valley Creek Apartments Location: 9085 Fairforest Road Spartanburg, SC 29301

Mailing Address: Same

County: Spartanburg

Previous Orders: 16-099-RW (\$680.00)

Permit/ID Number: 42-049-1

Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Two Bridges Valley Creek, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On May 22, 2017, and August 15, 2017, the pool was inspected and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: there was no drinking water fountain; there was no foot rinse shower; the bound and numbered log book was not maintained on a daily basis; the bathroom did not have toilet paper, soap, or paper towels; the chlorine level was not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; and the facility address was not posted at the emergency notification device.

Action: The Individual/Entity is required to: submit a corrective action plan and schedule of implementation to address the deficiencies; and pay a civil penalty in the amount of one thousand, three hundred sixty dollars (\$1,360.00).

23) Order Type and Number: Consent Order 17-122-RW

> Order Date: September 21, 2017 <u>Individual/Entity</u>: First Hospitality, LLC Facility: Days Inn Columbia Location: 1144 Bush River Road Columbia, SC 29210

> > Same

Mailing Address: County: Richland

Previous Orders: 16-016-RW (\$340.00)

Permit/ID Number: 40-043-1

Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: First Hospitality, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On June 16, 2017, and July 25, 2017, the pool was inspected and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: there was standing water on the pool deck and the deck was chipped; the gate did not self-close and latch; a section of the perimeter fencing was missing; the chlorine level was not within the acceptable range of water quality standards; the pool walls were dirty; the cyanuric acid level was above the water quality standards acceptable limit; and the cyanuric acid level was not monitored on a weekly basis.

Action: The Individual/Entity is required to: submit a corrective action plan and schedule of implementation to address the deficiencies; and pay a civil penalty in the amount of six hundred eighty dollars (\$680.00).

24) <u>Order Type and Number</u>: Consent Order 17-123-RW

Order Date: September 25, 2017

Individual/Entity:ASYM, Inc.Facility:Super 8 Motel

<u>Location</u>: 1515 Highway 101 South

Greer, SC 29651

Mailing Address: Same

<u>County</u>: Spartanburg

Previous Orders: None Permit/ID Number: 42-178-1

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-51(J)

<u>Summary</u>: ASYM, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On June 16, 2017, and July 20, 2017, the pool was inspected and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the pool rules sign was not completely filled out; the current pool operator of record information was not posted to the public; and the facility address was not posted at the emergency notification device.

Action: The Individual/Entity is required to: submit a corrective action plan and schedule of implementation to address the deficiencies; and pay a civil penalty in the amount of six hundred eighty dollars (\$680.00). The civil penalty has been paid. The Individual/Entity submitted a corrective action plan and corrected the deficiencies.

25) Order Type and Number: Consent Order 17-124-RW

Order Date: September 25, 2017

<u>Individual/Entity</u>: **Vitrag, Inc.**

Facility: Baymont Inn Duncan Location: 1546 East Main Street

Duncan, SC 29334

Mailing Address: Same

<u>County</u>: Spartanburg

<u>Previous Orders:</u> None <u>Permit/ID Number:</u> 42-191-1

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-51(J)

<u>Summary</u>: Vitrag, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On June 19, 2017, and July 20, 2017, the pool was inspected and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing a bolt cover; the chlorine level was not within the acceptable range of water quality standards; the life ring did not have a rope; the cyanuric acid level was above the water quality standards acceptable limit; the pool rules sign was not completely filled out; the current pool operator of record information was not posted to the public; and the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity is required to: submit a corrective action plan and schedule of implementation to address the deficiencies; and pay a civil penalty in the amount of six hundred eighty dollars (\$680.00).

26) <u>Order Type and Number</u>: Consent Order 17-126-RW

Order Date: September 26, 2017

Individual/Entity: Two Notch Hospitality, LLC

<u>Facility</u>: Best Western Plus Columbia North East

Location: 7525 Two Notch Road

Columbia, SC 29223

Mailing Address:SameCounty:RichlandPrevious Orders:NonePermit/ID Number:40-256-1

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-51(J)

Summary: Two Notch Hospitality, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On June 2, 2017, and June 6, 2017, the pool was inspected and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the deck was uneven with sharp edges; there was standing water on the deck; the pool furniture was not at least four feet from the edge of the pool; a skimmer was missing a weir; the drinking water fountain and foot rinse shower were not operating properly; there were chlorine sticks in a skimmer basket; the gate did not self-close and latch; the chlorine and pH levels were not within the acceptable range of water quality standards; and the disinfection equipment was leaking.

Action: The Individual/Entity is required to: submit a corrective action plan and schedule of implementation to address the deficiencies; and pay a civil penalty in the amount of six hundred eighty dollars (\$680.00).

Drinking Water Enforcement

27) <u>Order Type and Number</u>: Consent Order 17-022-DW

Order Date: September 8, 2017

Individual/Entity: Trinity Christian Academy

Facility: Trinity Christian Academy
Location: 2223 Harristown Road

St. Stephen, SC 29479

Mailing Address:SameCounty:BerkeleyPrevious Orders:NonePermit/ID Number:0870136

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-58.17.K(1)

<u>Summary</u>: Trinity Christian Academy (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS). On August 7, 2017, a violation was issued as a result of review of monitoring records. The Individual/Entity has violated the State Primary Drinking Water Regulations as follows: the PWS tested present for E. coli and the required repeat samples were not collected, which resulted in a violation of the maximum contaminant level (MCL) for E. coli.

<u>Action</u>: The Individual/Entity is required to: submit a standard operating procedure for monitoring and reporting requirements; submit a corrective action plan to include proposed steps to address the MCL violation; and pay a **stipulated penalty** in the amount of four thousand dollars **(\$4,000.00)** should any requirement of the Order not be met.

28) <u>Order Type and Number</u>: Consent Order 17-023-DW

Order Date: September 8, 2017

Individual/Entity:Mattamy Carolina CorporationFacility:Kings Grove Manor Subdivision

Location: 1224 Kings Grove Drive

York, SC 29745

Mailing Address: 2127 Ayrsley Town Boulevard

Charlotte, NC 28273

<u>County</u>: York <u>Previous Orders</u>: None Permit/ID Number: 30253-WS

Violations Cited: S.C. Code Ann. Regs. 61-58.1.K(1)

<u>Summary</u>: Mattamy Carolina Corporation (Individual/Entity) owns and is responsible for the proper construction and operation of a distribution system. On March 8, 2017, it was determined that the distribution system had been placed into operation without obtaining written approval to operate from the Department. The Individual/Entity has violated the State Primary Drinking Water Regulations as follows: failed to obtain written approval to operate from the Department prior to placing a distribution system into operation.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of one thousand dollars **(\$1,000.00)**. On June 27, 2017, the Department issued written approval to operate the distribution system. The civil penalty has been paid.

Water Pollution Enforcement

29) <u>Order Type and Number</u>: Consent Order 17-071-W

Order Date: September 5, 2017

Individual/Entity: South Carolina Department of Commerce

d.b.a Palmetto Railways

<u>Facility</u>: Charity Church Subdivision Wastewater

Treatment System (WWTS)

<u>Location</u>: 1047 Roundhouse Lane

Huger, SC 29450

Mailing Address: 540 East Bay Street

Charleston, SC 29403

County:BerkeleyPrevious Orders:NonePermit/ID Number:ND0082732

<u>Violations Cited</u>: Water Pollution Control Permits, Regs. 61-9.122.41 (a) (Supp. 2016) and Pollution Control Act, S.C. Code Ann. § 48-1-110(d) (Supp.

2016)

<u>Summary</u>: The South Carolina Department of Commerce d.b.a Palmetto Railways (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment system (WWTS) located in Berkeley County, South Carolina. On September 7, 2016, and March 6, 2017, Notices of Violation were issued as result of discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and the Water Pollution Control Permits Regulation in that it failed to comply with the effluent discharge limits of its National Pollutant Discharge Elimination System permit for pH.

<u>Action</u>: The Individual/Entity is required to: submit a corrective action plan to address the deficiencies; and, pay a civil penalty in the amount of two thousand, five hundred dollars **(\$2,500.00)**.

Dams Enforcement

30) Order Type and Number: Consent Agreement 17-069-W

Order Date:September 5, 2017Individual/Entity:Richard InmanFacility:Covingtons Lake Dam

<u>Location</u>: Approximately one-half (0.5) mile west from

the intersection of I-77 and Killian Road

<u>Mailing Address</u>: 620 Southlake Road

Columbia, SC 29223

County: Richland

<u>Previous Orders</u>: 2015 Emergency Order

Permit/ID Number: D 0545

<u>Law Citations</u>: SC Dams and Reservoirs Safety Act, S.C. Code Ann. § 49-11-110, *et seq.*, (2008) and Dams and Reservoirs Safety Act Regulation 72.1, *et seq.* (2012)

<u>Summary</u>: Richard Inman (Individual/Entity) owns and is responsible for the proper operation and maintenance of the Covingtons Lake Dam in Richland County, South Carolina. On October 15 2015, the Department issued an Emergency Order to the Individual/Entity as a result of unsafe conditions at the dam. The Agreement is entered into by the Department and the Individual/Entity with respect to remedial actions addressing deficiencies in the condition of the dam.

Action: The Individual/Entity is required to: maintain the Dam in a condition that does not impound water until the Dam is repaired or removed from the property; notify the Department upon any change in status, ownership, or condition of the Dam; apply for a permit prior to performing any changes to the Dam; and, obtain a permit under the "Construction Permit Application Requirements" in section 72-3.D.2, if plans are made to repair the Dam after a period of two (2) years from the execution date of the Order.

31) Order Type and Number: Consent Agreement 17-070-W

Order Date: September 5, 2017

<u>Individual/Entity</u>: **Little Pee Dee State Park**<u>Facility</u>: Pee Dee State Park Dam

<u>Location</u>: Located at the end of Park Access Road in the

Little Pee Dee State Park

Mailing Address: 1298 State Park Road

Dillon, SC 29536

County: Dillon

Previous Orders: 2016 Emergency Order

Permit/ID Number: D 3602

<u>Law Citations</u>: SC Dams and Reservoirs Safety Act, S.C. Code Ann. § 49-11-110, *et seq.*, (2008) and Dams and Reservoirs Safety Act Regulation 72.1,

et seq. (2012)

<u>Summary</u>: Little Pee Dee State Park (Individual/Entity) owns and is responsible for the proper operation and maintenance of the Pee Dee State Park Dam in Dillon County, South Carolina. On October 9 2016, the Department issued an Emergency Order to the Individual/Entity as a result of unsafe conditions at the dam. The Agreement is entered into by the Department and the Individual/Entity with respect to remedial actions addressing deficiencies in the condition of the dam.

Action: The Individual/Entity is required to: maintain the Dam in a condition that does not impound water until the Dam is repaired or removed from the property; notify the Department upon any change in status, ownership, or condition of the Dam; apply for a permit prior to performing any changes to the Dam; and, obtain a permit under the "Construction Permit Application Requirements" in section 72-3.D.2, if plans are made to repair the Dam after a period of two (2) years from the execution date of the Order.

32) <u>Order Type and Number</u>: Consent Agreement 17-072-W

Order Date: September 26, 2017

<u>Individual/Entity</u>: Shannon Shepard and Lea Shepard

<u>Facility</u>: L P Pitts Dam

<u>Location</u>: Approximately one-half (0.5) mile

northeast from the intersection of

Greenwood Highway and Dillard Road

Mailing Address: 1680 Rocky Ridge Road

Enoree, SC 29335

County: Laurens

Previous Orders: 2015 Emergency Order

Permit/ID Number: D 4528

<u>Law Citations</u>: SC Dams and Reservoirs Safety Act, S.C. Code Ann. § 49-11-110, *et seq.*, (2008) and Dams and Reservoirs Safety Act Regulation 72.1,

et seq. (2012)

<u>Summary</u>: Shannon Shepard and Lea Shepard (Individuals/Entities) own and are responsible for the proper operation and maintenance of the L P Pitts Dam in Laurens County, South Carolina. On October 15, 2015, the Department issued an Emergency Order to the Individuals/Entities as a result of unsafe conditions at the dam. The Agreement is entered into by the Department and the Individuals/Entities with respect to remedial actions addressing deficiencies in the condition of the dam.

Action: The Individuals/Entities are required to: maintain a lowered water level in the reservoir until Certification of Completion is issued by the Department; submit a permit application prepared by a qualified registered professional engineer licensed to practice in South Carolina for the repair or removal of the Dam; submit documentation that all local, state, and federal permit applications have been submitted; and, complete all construction activities with approved plans for the repair or removal of the Dam.

BUREAU OF AIR QUALITY

33) <u>Order Type and Number</u>: Consent Order 17-030-A

Order Date: September 12, 2017
Individual/Entity: Central Wire, Inc.
Facility: Central Wire, Inc.

<u>Location</u>: 1552 Cedar Pines Lake Road

Lancaster, SC 29720

Mailing Address:SameCounty:LancasterPrevious Orders:NonePermit/ID Number:1460-0024

<u>Violations Cited</u>: 5 S.C. Code Ann. Regs 61-62.1, Section II, Permit

Requirements, and 5 S.C. Code Ann. Regs. 61-62.1, Section II.A.1.a

Summary: Central Wire, Inc. (Individual/Entity), located in Lancaster, South Carolina, manufactures wire. On June 2, 2017, the Department conducted a comprehensive inspection at the Individual/Entity. The Individual/Entity has violated South Carolina Air Pollution Control Regulations as follows: failed to operate a control device from September 2016 until June 2017 when processes controlled by the control device operated; failed to maintain records of operation and maintenance checks on the control devices from September 2014 until June 2017; and, failed to obtain a construction permit from the Department prior to installing an additional control device.

Action: The Individual/Entity is required to: operate the control devices whenever processes controlled by the control devices are operating; maintain records of operation and maintenance checks on the control devices; obtain a construction permit from the Department prior to constructing, altering or adding to a source of air contaminants; and, pay a civil penalty in the amount of four thousand dollars (\$4,000.00) to the Department.

Consent Order 17-031-A 34) Order Type and Number: Order Date: September 12, 2017

> **Individual/Entity**: Falcon Boats, LLC, D.B.A. Falcon Bass Boats

Facility: Falcon Bass Boats Location: 750 Wilson Road

Newberry, SC 29108

Mailing Address: Same County: Newberry **Previous Orders:** None Permit/ID Number: 1780-0054

Requirements

Violations Cited: U.S. EPA 40 CFR 70.5(a)(1)(ii)), 5 S.C. Code Ann. Regs. 61-62.70.5(a)(1)(ii), and 5 S.C. Code Ann. Regs. 61-62.1, Section II, Permit

Summary: Falcon Boats, LLC, D.B.A. Falcon Bass Boats (Individual/Entity), located in Newberry, South Carolina, manufactures fiberglass boats. On February 23, 2016, the Department issued Construction Permit 1780-0054-CA to the Individual/Entity. On June 30, 2017, the Department received a Title V Permit Application from the Individual/Entity; however, the application was due no later than June 4, 2016. The Individual/Entity has violated U.S. EPA Regulations at 40 CFR and South Carolina Air Pollution Control Regulations as follows: failed to submit a complete Title V Permit Application to the Department within 12 months after commencing operation.

Action: The Individual/Entity is required to: comply with all terms and conditions of Construction Permit 1780-0054-CA, until such time as the Department takes final action on the Title V Permit application; and, pay a civil penalty in the amount of five thousand dollars (**\$5,000.00**) to the Department.

BUREAU OF ENVIRONMENTAL HEALTH SERVICES

Food Safety Enforcement

35) <u>Order Type and Number</u>: Administrative Order 2016-206-07-065

Order Date:September 8, 2017Individual/Entity:Tavern and TableFacility:Tavern and TableLocation:100 Church Street

Mount Pleasant, SC 29464

Mailing Address:SameCounty:CharlestonPrevious Orders:None

<u>Permit Number:</u> 10-206-09406

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Tavern and Table (Individual/Entity) is a restaurant located in Mount Pleasant, South Carolina. The Department conducted inspections on July 18, 2016, and July 25, 2016. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of one thousand dollars (\$1,000.00).

36) Order Type and Number: Administrative Order 2017-206-07-006

Order Date:September 8, 2017Individual/Entity:Sand Shack Bar & GrillFacility:Sand Shack Bar & GrillLocation:5090 Ashley Phosphate Road

North Charleston, SC 29418

Mailing Address:SameCounty:DorchesterPrevious Orders:None

<u>Permit Number:</u> 18-206-06817

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Sand Shack Bar & Grill (Individual/Entity) is a restaurant located in North Charleston, South Carolina. The Department conducted inspections on March 29, 2016, April 11, 2016, February 28, 2017, and March 10, 2017. Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to provide a written plan for the restriction, exclusion and re-instatement of food employees when they have symptoms and/or diseases that are transmissible through food.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of one thousand dollars (\$1,000.00).

37) Order Type and Number: Consent Order 2016-206-03-109

Order Date: September 1, 2017

Individual/Entity: Hunan Wok
Facility: Hunan Wok

<u>Location</u>: 7467 St. Andrews Road, Suite 4

Irmo, SC 29063

Mailing Address: Same County: Lexington

<u>Previous Orders</u>: 2015-206-03-119 (\$800.00)

<u>Permit Number</u>: 32-206-06354

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Hunan Wok (Individual/Entity) is a restaurant located in Irmo, South Carolina. The Department conducted inspections on November 12, 2015, May 27, 2016, and December 1, 2016. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods; and failed to use effective methods to cool cooked time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of one thousand, two hundred dollars (\$1,200.00).

38) Order Type and Number: Consent Order 2016-206-03-115

Order Date:September 1, 2017Individual/Entity:Quickserve 2Facility:Quickserve 2Location:108 Main Street

Gilbert, SC 29054

Mailing Address: P.O. Box 2066

Lexington, SC 29071

<u>County</u>: Lexington <u>Previous Orders</u>: None

Permit Number: 32-206-04477

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Quickserve 2 (Individual/Entity) is a convenience store located in Gilbert, South Carolina. The Department conducted inspections on December 7, 2015, October 19, 2016, and October 21, 2016. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of five hundred fifty dollars (\$550.00).

39) Order Type and Number: Consent Order 2016-206-03-118

Order Date:September 1, 2017Individual/Entity:Bi-Lo #5558 DeliFacility:Bi-Lo #5558 Deli

<u>Location</u>: 249 West Columbia Avenue

Batesburg, SC 29006

Mailing Address: P.O. Box 2209

Jacksonville, FL 32203

<u>County</u>: Lexington <u>Previous Orders</u>: None

<u>Permit Number:</u> 32-206-02779

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Bi-Lo #5558 Deli (Individual/Entity) is a deli located in Batesburg, South Carolina. The Department conducted inspections on October 19, 2016, October 26, 2016, November 7, 2016, and November 17, 2016. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows failed to maintain the premises free of insects, rodents, and other pests.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

40) Order Type and Number: Consent Order 2016-206-08-040

Order Date:September 1, 2017Individual/Entity:Chicken LickenFacility:Chicken Licken

Location: 16161 Whyte Hardee Boulevard

Hardeeville, SC 29927

Mailing Address: 246 Florida Drive

Hardeeville, SC 29927

<u>County</u>: Jasper

Previous Orders: 2016-206-08-014 (\$800)

Permit Number: 27-206-00521

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Chicken Licken (Individual/Entity) is a restaurant located in Hardeeville, South Carolina. The Department conducted inspections on March 16, 2016, August 5, 2016, August 15, 2016, and August 25, 2016. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods; failed to properly cool cooked time/temperature control for safety foods; and failed to follow the requirements of Barbecue Pit and Pit-Cooking room construction.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of two thousand, six hundred dollars (\$2,600.00).

41) Order Type and Number: Consent Order 2017-206-01-016

Order Date:September 1, 2017Individual/Entity:Kenny's HomecookingFacility:Kenny's HomecookingLocation:711 Anderson Drive

Williamston, SC 29697

<u>Mailing Address</u>: Same <u>County</u>: Anderson

<u>Previous Orders</u>: 2016-206-01-044 (\$800.00)

<u>Permit Number</u>: 04-206-03692

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

Summary: Kenny's Homecooking (Individual/Entity) is a restaurant located in Williamston, South Carolina. The Department conducted inspections on April 25, 2016, February 14, 2017, and June 8, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods; failed to clean the physical facilities as often as necessary to keep them clean; failed to keep food contact surfaces, nonfood contact surfaces, and utensils clean and free of accumulation of dust, dirt, food residue and other debris; and failed to frequently clean the warewashing machine; the compartments of sinks, basins or other receptacles used for washing and rinsing equipment, utensils, raw foods or laundering wiping cloths; and drainboards.

<u>Action</u>: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of one thousand, five hundred dollars (\$1,500.00).

42) <u>Order Type and Number</u>: Consent Order 2017-206-02-009

Order Date:September 1, 2017Individual/Entity:Waffle House #1667Facility:Waffle House #1667Location:1 Melvin Drive

Greenville, SC 29605

Mailing Address: P.O. Box 6450

Norcross, GA 30091

<u>County</u>: Greenville <u>Previous Orders</u>: None

<u>Permit Number:</u> 23-206-08642

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Waffle House #1667 (Individual/Entity) is a restaurant located in Greenville, South Carolina. The Department conducted inspections on February 26, 2016, January 24,

2017, and February 3, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to keep food contact surfaces, nonfood contact surfaces and utensils clean and free of accumulation of dust, dirt, food residue and other debris.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of two hundred dollars (\$200.00).

43) Order Type and Number: Consent Order 2017-206-02-023

Order Date:September 1, 2017Individual/Entity:Trattoria GiorgioFacility:Trattoria Giorgio

<u>Location</u>: 121 South Main Street

Greenville, SC 29601

Mailing Address:SameCounty:GreenvillePrevious Orders:None

<u>Permit Number</u>: 23-206-06419

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Trattoria Giorgio (Individual/Entity) is a restaurant located in Greenville, South Carolina. The Department conducted inspections on December 21, 2015, September 26, 2016, and July 12, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to clean ice bins and beverage dispensing nozzles and enclosed components of equipment such as ice makers, cooking oil storage tanks and distribution lines, beverage and syrup dispensing lines or tubes, coffee bean grinders, and water vending equipment at a frequency specified by the manufacturer, or at a frequency necessary to preclude accumulation of soil or mold.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of two hundred dollars (\$200.00).

44) <u>Order Type and Number</u>: Consent Order 2017-206-02-024

Order Date: September 1, 2017
Individual/Entity: Commerce Club
Facility: Commerce Club

<u>Location</u>: 55 Beattie Place, 17th Floor

Greenville, SC 29601

Mailing Address:SameCounty:GreenvillePrevious Orders:None

<u>Permit Number</u>: 23-206-04217

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

Summary: Commerce Club (Individual/Entity) is a restaurant located in Greenville, South Carolina. The Department conducted inspections on January 5, 2016, October 19, 2016, and July 20, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to clean ice bins and beverage dispensing nozzles and enclosed components of equipment such as ice makers, cooking oil storage tanks and distribution lines, beverage and syrup dispensing lines or tubes, coffee bean grinders, and water vending equipment at a frequency specified by the manufacturer, or at a frequency necessary to preclude accumulation of soil or mold.

<u>Action</u>: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of two hundred dollars **(\$200.00)**.

45) <u>Order Type and Number</u>: Consent Order 2017-206-03-021

Order Date:September 1, 2017Individual/Entity:Hamm's Hawg HeavenFacility:Hamm's Hawg HeavenLocation:11375 CR Koon Highway

Prosperity, SC 29127

Mailing Address: PO Box 919

Prosperity, SC 29127

County: Newberry

<u>Previous Orders</u>: 2015-206-03-055 (\$800.00)

2016-206-03-021 (\$600.00)

Permit Number: 36-206-01008

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Hamm's Hawg Heaven (Individual/Entity) is a restaurant located in Prosperity, South Carolina. The Department conducted an inspection on February 24, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

<u>Action</u>: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of one thousand dollars **(\$1,000.00)**.

46) Order Type and Number: Consent Order 2017-206-03-042

Order Date:September 1, 2017Individual/Entity:Fatz Café #27Facility:Fatz Café #27

<u>Location</u>: 478 Herlong Avenue

Rock Hill, SC 29732

Mailing Address: 4324 Wade Hampton Boulevard, Suite B

Taylors, SC 29687

County: York

<u>Previous Orders</u>: 2015-206-03-073 (\$800.00)

<u>Permit Number</u>: 46-206-00413

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Fatz Café #27 (Individual/Entity) is a restaurant located in Rock Hill, South Carolina. The Department conducted an inspection on March 29, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of one thousand, two hundred dollars (\$1,200.00).

47) Order Type and Number: Consent Order 2017-206-03-044

Order Date:September 1, 2017Individual/Entity:Fatz Café #20Facility:Fatz Café #20

<u>Location</u>: 7420 Broad River Road

Irmo, SC 29063

Mailing Address: 4324 Wade Hampton Blvd., Suite B

Taylors, SC 29687

<u>County</u>: Richland <u>Previous Orders</u>: None

<u>Permit Number</u>: 40-206-04993

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Fatz Café #20 (Individual/Entity) is a restaurant located in Irmo, South Carolina. The Department conducted inspections on March 9, 2016, February 27, 2017, and July 14, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to properly cool cooked time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

48) Order Type and Number: Consent Order 2017-206-03-045

Order Date:September 1, 2017Individual/Entity:Springdale CFacility:Springdale C

<u>Location</u>: 1130 Springdale Road

Rock Hill, SC 29730

Mailing Address:SameCounty:YorkPrevious Orders:None

<u>Permit Number</u>: 46-206-03139

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Springdale C (Individual/Entity) is a restaurant located in Rock Hill, South Carolina. The Department conducted inspections on March 10, 2017, March 17, 2017, and June 14, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

49) Order Type and Number: Consent Order 2017-206-03-052

Order Date: September 1, 2017

Individual/Entity:Ray's Pizzeria & Ice CreamFacility:Ray's Pizzeria & Ice CreamLocation:5140 Sunset Boulevard, Suite E

Lexington, SC 29072

Mailing Address:SameCounty:LexingtonPrevious Orders:None

<u>Permit Number:</u> 32-206-05475

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Ray's Pizzeria & Ice Cream (Individual/Entity) is a restaurant located in Lexington, South Carolina. The Department conducted inspections on March 18, 2016, March 10, 2017, and March 17, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

50) Order Type and Number: Consent Order 2017-206-06-052

Order Date: September 1, 2017

Individual/Entity:Valentino Italian RestaurantFacility:Valentino Italian RestaurantLocation:323 Highway 17 North

Surfside Beach, SC 29575

Mailing Address:SameCounty:HorryPrevious Orders:None

<u>Permit Number</u>: 26-206-11890

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Valentino Italian Restaurant (Individual/Entity) is a restaurant located in Surfside Beach, South Carolina. The Department conducted inspections on June 13, 2016,

January 26, 2017, and July 3, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to use effective methods to cool cooked time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of four hundred dollars (\$400.00).

51) <u>Order Type and Number</u>: Consent Order 2017-206-07-019

Order Date: September 1, 2017

Individual/Entity:El Mercadito & TaqueriaFacility:El Mercadito & Taqueria

<u>Location</u>: 3575 Maybank Highway, Suite N

Johns Island, SC 29455

Mailing Address:SameCounty:CharlestonPrevious Orders:None

<u>Permit Number</u>: 10-206-04959

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: El Mercadito & Taqueria (Individual/Entity) is a restaurant located in Johns Island, South Carolina. The Department conducted inspections on March 16, 2017, June 7, 2017, June 15, 2017, June 22, 2017, June 26, 2017, and July 6, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods; failed to properly cool cooked time/temperature control for safety foods; failed to store foods in a manner to prevent cross contamination; failed to use effective methods to cool cooked time/temperature control for safety foods; failed to have no priority violations during the inspection; and failed to clearly mark the date or day by which food shall be consumed on the premises, sold or discarded when held at a temperature of 41°F or less for a maximum of seven (7) days, on the refrigerated, ready-to-eat time/temperature control for safety food prepared and held in a food establishment for more than twenty four (24) hours.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of three thousand dollars (\$3,000.00).

52) <u>Order Type and Number</u>: Consent Order 2017-206-08-003

Order Date: September 1, 2017

<u>Individual/Entity</u>: **Poseidon Coastal Cuisine** <u>Facility</u>: Poseidon Coastal Cuisine

<u>Location</u>: 38 Shelter Cove Lane, Suite 121

Hilton Head Island, SC 29928

Mailing Address:SameCounty:BeaufortPrevious Orders:None

Permit Number: 07-206-09960

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Poseidon Coastal Cuisine (Individual/Entity) is a restaurant located in Hilton Head Island, South Carolina. The Department conducted inspections on August 18, 2015, August 15, 2016, and July 31, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

53) Order Type and Number: Consent Order 2016-206-01-051

Order Date:September 6, 2017Individual/Entity:Tony's Pizza and SubsFacility:Tony's Pizza and SubsLocation:1722 Highway 86

Piedmont, SC 29673

Mailing Address:SameCounty:AndersonPrevious Orders:None

<u>Permit Number</u>: 04-206-04256

Violations Cited: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Tony's Pizza and Subs (Individual/Entity) is a restaurant located in Piedmont, South Carolina. The Department conducted inspections on October 21, 2015, August 23, 2016, and September 2, 2016. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to clean non-food contact surfaces at a frequency to preclude accumulation of soil residues.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of two hundred dollars (\$200.00).

54) Order Type and Number: Consent Order 2016-208-03-001

Order Date: September 6, 2017

Individual/Entity:Fort Mill Elementary SchoolFacility:Fort Mill Elementary SchoolLocation:192 Springfield Parkway

Fort Mill, SC 29715

Mailing Address:SameCounty:YorkPrevious Orders:None

<u>Permit Number</u>: 46-206-01721

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Fort Mill Elementary School (Individual/Entity) operates a cafeteria located in Fort Mill, South Carolina. The Department conducted inspections on May 2, 2016, October 7, 2016, and March 2, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of five hundred fifty dollars (\$550.00).

55) <u>Order Type and Number</u>: Consent Order 2017-206-01-019

Order Date: September 6, 2017

Individual/Entity: Blockhouse Restaurant @ Auto Auction
Facility: Blockhouse Restaurant @ Auto Auction

<u>Location</u>: 140 Webb Road

Williamston, SC 29697

Mailing Address: 1619 August Street

Greenville, SC 29605

<u>County</u>: Anderson Previous Orders: None

Permit Number: 04-206-03554

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Blockhouse Restaurant @ Auto Auction (Individual/Entity) is a restaurant located in Williamston, South Carolina. The Department conducted inspections on March 18, 2015, March 2, 2016, and February 8, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to clearly and individually identify with the common name of the material on all working containers used for storing poisonous or toxic materials, such as cleaners and sanitizers, taken from bulk supplies.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of four hundred dollars (\$400.00).

56) <u>Order Type and Number</u>: Consent Order 2017-206-02-022

Order Date: September 6, 2017

Individual/Entity:Victoria Valley VineyardsFacility:Victoria Valley VineyardsLocation:1360 South Saluda Road

Cleveland, SC 29635

Mailing Address: Same County: Pickens

<u>Previous Orders:</u> None

<u>Permit Number</u>: 39-206-01471

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Victoria Valley Vineyards (Individual/Entity) operates a restaurant located in Cleveland, South Carolina. The Department conducted inspections on May 18, 2017, June 8, 2017, and June 22, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods; and failed to ensure that live animals may not be allowed on the premises of retail food establishment unless the animal meets the regulatory requirement of being served in the restaurant as food, contained in an aquarium, or a service animal.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

57) <u>Order Type and Number</u>: Consent Order 2017-206-03-025

Order Date: September 6, 2017

<u>Individual/Entity</u>: **Jomars** <u>Facility</u>: Jomars

<u>Location</u>: 278 Lancaster Bypass East

Lancaster, SC 29720

Mailing Address: Same
County: Lancaster

<u>Previous Orders</u>: 2016-206-03-017 (\$800.00)

Permit Number: 29-206-01031

Violations Cited: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Jomars (Individual/Entity) is a restaurant located in Lancaster, South Carolina. The Department conducted an inspection on May 18, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of one thousand dollars (\$1,000.00).

58) Order Type and Number: Consent Order 2017-206-03-043

Order Date:September 6, 2017Individual/Entity:Ruby Tuesday #4439Facility:Ruby Tuesday #4439Location:511 Bush River Road

Columbia, SC 29210

Mailing Address: 150 West Church Avenue

Maryville, TN 37801

County: Richland

<u>Previous Orders:</u> None

<u>Permit Number</u>: 40-206-05102

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Ruby Tuesday #4439 (Individual/Entity) is a restaurant located in Columbia, South Carolina. The Department conducted inspections on April 29, 2016, March 21, 2017, and March 28, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

59) Order Type and Number: Consent Order 2017-206-03-047

Order Date: September 6, 2017

Individual/Entity:Kentucky Fried Chicken #05Facility:Kentucky Fried Chicken #05Location:2340 Decker Boulevard

Columbia, SC 29206

Mailing Address: 1245 Boston Avenue

West Columbia, SC 29170

<u>County</u>: Richland <u>Previous Orders</u>: None

Permit Number: 40-206-02977

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Kentucky Fried Chicken #05 (Individual/Entity) is a restaurant located in Columbia, South Carolina. The Department conducted inspections on April 11, 2016, April 11, 2017, and April 19, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure floors, floor coverings, walls, wall coverings, and ceilings were designed, constructed, and installed so they are smooth and easily cleanable.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of two hundred dollars (\$200.00).

60) Order Type and Number: Consent Order 2017-206-03-022

Order Date: September 8, 2017
Individual/Entity: Lizard's Thicket #04
Facility: Lizard's Thicket #04
Location: 7411 Nates Road
Columbia, SC 29223

1036 Market Street Columbia, SC 29201

County: Richland

Mailing Address:

Previous Orders: 2015-206-03-105 (\$800.00)

Permit Number: 40-206-01085

Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Lizard's Thicket #04 (Individual/Entity) is a restaurant located in Columbia, South Carolina. The Department conducted an inspection on April 4, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of one thousand dollars (\$1,000.00).

61) Order Type and Number: Consent Order 2017-206-03-031

September 8, 2017 Order Date:

Individual/Entity: **Tuskers** Facility: Tuskers

Location: 500 Wildlife Parkway

Columbia, SC 29210

Mailing Address: Same County: Richland **Previous Orders:** None

Permit Number: 40-206-07286

Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Tuskers (Individual/Entity) is a restaurant located in Columbia, South Carolina. The Department conducted inspections on May 30, 2017, May 31, 2017, and July 17, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

Consent Order 2017-206-03-036 62) Order Type and Number:

Order Date: September 8, 2017

Individual/Entity: 903 Drive-In Restaurant Facility: 903 Drive-In Restaurant Location: 1445 Flat Creek Road Lancaster, SC 29720

Mailing Address: P.O. Box 1171

Lancaster, SC 29721

County: Lancaster **Previous Orders:** None

Permit Number: 29-206-00363 <u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: 903 Drive-In Restaurant (Individual/Entity) is a restaurant located in Lancaster, South Carolina. The Department conducted inspections on January 13, 2016, January 3, 2017, and January 12, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

63) Order Type and Number: Consent Order 2017-206-08-002

Order Date:September 8, 2017Individual/Entity:Joe Loves Lobster RollFacility:Joe Loves Lobster RollLocation:2915 Okatie Highway

Ridgeland, SC 29936

Mailing Address:SameCounty:BeaufortPrevious Orders:None

<u>Permit Number</u>: 27-206-00594

Violations Cited: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Joe Loves Lobster Roll (Individual/Entity) is a restaurant located in Ridgeland, South Carolina. The Department conducted inspections on March 31, 2017, April 11, 2017, and April 14, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

64) Order Type and Number: Consent Order 2017-206-03-038

Order Date:September 12, 2017Individual/Entity:Big T's Bar-B-QFacility:Big T's Bar-B-QLocation:2520 Congaree Road

Gadsden, SC 29052

Mailing Address:SameCounty:RichlandPrevious Orders:None

<u>Permit Number:</u> 40-206-01451

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Big T's Bar-B-Q (Individual/Entity) is a restaurant located in Gadsden, South Carolina. The Department conducted inspections on February 3, 2017, February 16, 2017, and February 22, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

65) Order Type and Number: Consent Order 2017-206-03-040

Order Date: September 12, 2017
Individual/Entity: Urban Cookhouse
Facility: Urban Cookhouse

<u>Location</u>: 1072 Lake Murray Boulevard

Irmo, SC 29063

Mailing Address: P.O. Box 61108

Columbia, SC 29260

<u>County</u>: Lexington Previous Orders: None

<u>Permit Number:</u> 32-206-06588

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Urban Cookhouse (Individual/Entity) is a restaurant located in Irmo, South Carolina. The Department conducted inspections on February 23, 2017, March 1, 2017, and March 8, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

66) Order Type and Number: Consent Order 2017-206-03-046

Order Date: September 12, 2017

Individual/Entity:Earth Fare #250 Deli/CaféFacility:Earth Fare #250 Deli/CaféLocation:725 Cherry Road, Suite 110

Rock Hill, SC 29730

Mailing Address: 220 Continuum Drive

Fletcher, NC 28732

<u>County</u>: York <u>Previous Orders:</u> None

<u>Permit Number:</u> 46-206-02438

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Earth Fare #250 Deli/Café (Individual/Entity) is a deli located in Rock Hill, South Carolina. The Department conducted inspections on December 15, 2016, December 22, 2016, and May 12, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

67) Order Type and Number: Consent Order 2016-206-03-120

Order Date:September 14, 2017Individual/Entity:Papa John's PizzaFacility:Papa John's Pizza

<u>Location</u>: 6257 Carolina Commons Drive

Indian Land, SC 29707

Mailing Address: P.O. Box 8000

Monsey, NC 10952

<u>County</u>: Lancaster Previous Orders: None

<u>Permit Number</u>: 29-206-01511

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Papa John's Pizza (Individual/Entity) is a restaurant located in Indian Land, South Carolina. The Department conducted inspections on October 18, 2016, October 27, 2016, and November 3, 2016. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the premises free of insects, rodents, and other pests.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of four hundred dollars (\$400.00).

68) Order Type and Number: Consent Order 2016-206-03-123

Order Date:September 14, 2017Individual/Entity:Taqueria El ManhattanFacility:Taqueria El ManhattanLocation:1618 Memorial Park Road

Lancaster, SC 29720

Mailing Address:SameCounty:LancasterPrevious Orders:None

<u>Permit Number</u>: 29-206-01465

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Taqueria El Manhattan (Individual/Entity) is a restaurant located in Lancaster, South Carolina. The Department conducted inspections on January 26, 2016,

October 12, 2016, and October 20, 2016. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to properly cool, cooked time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

69) <u>Order Type and Number</u>: Consent Order 2016-206-03-125

Order Date:September 14, 2017Individual/Entity:Taqueria El ManhattanFacility:Taqueria El ManhattanLocation:1919 Cherry Road

Rock Hill, SC 29732

Mailing Address: Same
County: York
Previous Orders: None

Permit Number: 46-206-03445

Violations Cited: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Taqueria El Manhattan (Individual/Entity) is a restaurant located in Rock Hill, South Carolina. The Department conducted inspections on September 14, 2016, November 9, 2016, and November 15, 2016. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods; and failed to ensure that when time without temperature control is used as a public health control, the food in unmarked containers or packages shall be discarded.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

70) Order Type and Number: Consent Order 2017-206-03-028

Order Date:September 14, 2017Individual/Entity:Corner Mart #44Facility:Corner Mart #44Location:12780 SC Highway 121

Newberry, SC 29801

Mailing Address: P.O. Box 2969

Greenville, SC 29602

County: Newberry

Previous Orders: 2016-206-03-111 (\$800.00)

<u>Permit Number:</u> 36-206-00895

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Corner Mart #44 (Individual/Entity) is a convenience store located in Newberry, South Carolina. The Department conducted inspections on July 26, 2017, and August 2, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of two thousand dollars (\$2,000.00).

71) Order Type and Number: Consent Order 2017-206-03-029

Order Date:September 14, 2017Individual/Entity:RNK CatawbaFacility:RNK CatawbaLocation:5595 Highway 5

Catawba, SC 29704

Mailing Address: P.O. Box 1317

Lancaster, SC 29721

<u>County</u>: York

<u>Previous Orders</u>: 2016-206-03-056 (\$800.00)

<u>Permit Number</u>: 46-206-03381

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: RNK Catawba (Individual/Entity) is a convenience store located in Catawba, South Carolina. The Department conducted inspections on July 21, 2017, and August 11, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of two thousand dollars **(\$2,000.00)**.

72) Order Type and Number: Consent Order 2017-206-03-034

Order Date: September 14, 2017
Individual/Entity: Korner Kupboard II
Facility: Korner Kupboard II
Location: 503 North Matson Street

Kershaw, SC 29067

Mailing Address:SameCounty:Lancaster

<u>Previous Orders</u>: 2016-206-03-012 (\$800.00)

<u>Permit Number:</u> 29-206-00647

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Korner Kupboard II (Individual/Entity) is a convenience store located in Kershaw, South Carolina. The Department conducted an inspection on January 10, 2017. The

Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of one thousand dollars (\$1,000.00).

73) <u>Order Type and Number</u>: Consent Order 2017-206-03-035

Order Date:September 14, 2017Individual/Entity:Lake Wylie GrillFacility:Lake Wylie Grill

<u>Location</u>: 4074 Charlotte Highway

Lake Wylie, SC 29710

Mailing Address: P.O. Box 5242

Lake Wylie, SC 29710

<u>County</u>: York <u>Previous Orders</u>: None

<u>Permit Number</u>: 46-206-00503

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Lake Wylie Grill (Individual/Entity) is a restaurant located in Lake Wylie, South Carolina. The Department conducted inspections on January 19, 2017, January 20, 2017, and January 27, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

74) Order Type and Number: Consent Order 2017-206-03-039

Order Date: September 14, 2017

Individual/Entity: IHOP #3184
Facility: IHOP #3184

<u>Location</u>: 5571 Sunset Boulevard

Lexington, SC 29072

Mailing Address: 2704 Prathers Creek Church Road

Laurel Springs, NC 28644

<u>County</u>: Lexington <u>Previous Orders</u>: None

<u>Permit Number</u>: 32-206-05300

Violations Cited: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: IHOP #3184 (Individual/Entity) is a restaurant located in Lexington, South Carolina. The Department conducted inspections on April 27, 2015, April 11, 2016, and March 15, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment

Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of five hundred fifty dollars (\$550.00).

75) <u>Order Type and Number</u>: Consent Order 2017-206-03-049

Order Date:September 14, 2017Individual/Entity:Comfort SuitesFacility:Comfort SuitesLocation:1540 Daulton Drive

Columbia, SC 29223

Mailing Address:SameCounty:RichlandPrevious Orders:None

<u>Permit Number</u>: 40-206-06313

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Comfort Suites (Individual/Entity) is a hotel that operates a restaurant located in Columbia, South Carolina. The Department conducted inspections on June 18, 2015, May 19, 2016, and April 4, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to provide individual disposable towels, a continuous towel system that supplies the user with a clean towel, a heated air hand drying device or a hand-drying device that employs an air-knife system that delivers high velocity, pressurized air at ambient temperatures at each hand washing sink or group of adjacent handwashing sinks.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of four hundred dollars (\$400.00).

76) Order Type and Number: Consent Order 2017-206-06-022

Order Date: September 14, 2017
Individual/Entity: Jimmy Johns
Facility: Jimmy Johns

<u>Location</u>: 2108 North Kings Highway

Myrtle Beach, SC 29577

Mailing Address: 1200 Yaupon Drive #8

Myrtle Beach, SC 29577

<u>County</u>: Horry <u>Previous Orders</u>: None

<u>Permit Number</u>: 26-206-10017

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Jimmy Johns (Individual/Entity) is a restaurant located in Myrtle Beach, South Carolina. The Department conducted inspections on October 27, 2016, November 7, 2016, and April 5, 2017. The Individual/Entity has violated the South Carolina Retail Food

Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of six hundred ninety dollars (\$690.00).

77) <u>Order Type and Number</u>: Consent Order 2017-206-06-039

Order Date: September 14, 2017

Individual/Entity:Michael's Pizza, Pasta and GrillFacility:Michael's Pizza, Pasta and GrillLocation:1701 North Kings Highway

Myrtle Beach, SC 29577

Mailing Address: Same County: Horry

<u>Previous Orders:</u> 2015-206-06-001 (\$1,750.00)

2016-206-06-005 (\$1,200.00)

<u>Permit Number</u>: 26-206-07160

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

Summary: Michael's Pizza, Pasta and Grill (Individual/Entity) is a restaurant located in Myrtle Beach, South Carolina. The Department conducted inspections on March 9, 2017, March 16, 2017, and March 24, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods; and failed to clearly mark the date or day by which food shall be consumed on the premises, sold, or discarded when held at a temperature of 41°F or less for a maximum of seven (7) days, on the refrigerated, ready-to-eat, time/temperature control for safety food prepared and held in a food establishment for more than twenty four (24) hours.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of four thousand, five hundred sixty dollars (\$4,560.00).

78) Order Type and Number: Consent Order 2017-206-06-049

Order Date:September 14, 2017Individual/Entity:McDonald's #26233Facility:McDonald's #26233Location:596 Highway 701 North

Loris, SC 29569

Mailing Address: 171 McDonald Court

Myrtle Beach, SC 29588

County: Horry

<u>Previous Orders</u>: 2016-206-063 (\$1,200.00)

Permit Number: 26-206-08301

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: McDonald's #26233 (Individual/Entity) is a restaurant located in Loris, South Carolina. The Department conducted inspections on June 21, 2017, and June 30, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure written procedures were in place and made available to the Department when the facility uses Time as a Public Health Control.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of two thousand dollars (\$2,000.00).

79) <u>Order Type and Number</u>: Consent Order 2017-206-06-050

Order Date: September 14, 2017

Individual/Entity:New Ho Wah Restaurant Inc.Facility:New Ho Wah Restaurant Inc.Location:409 South Kings Highway

Myrtle Beach, SC 29577

Mailing Address:SameCounty:HorryPrevious Orders:None

<u>Permit Number</u>: 26-206-08598

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: New Ho Wah Restaurant Inc. (Individual/Entity) is a restaurant located in Myrtle Beach, South Carolina. The Department conducted inspections on November 10, 2016, February 15, 2017, June 29, 2017, and July 3, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods; and failed to properly cool, cooked time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of one thousand, six hundred dollars (\$1,600.00).

80) Order Type and Number: Consent Order 2016-206-03-124

Order Date:September 15, 2017Individual/Entity:Spot Food Store #2Facility:Spot Food Store #2Location:103 Pinckney Street

Chester, SC 29706

Mailing Address:SameCounty:ChesterPrevious Orders:None

<u>Permit Number:</u> 12-206-00389

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Spot Food Store #2 (Individual/Entity) is a convenience store located in Chester, South Carolina. The Department conducted inspections on September 20, 2016,

October 13, 2016, and October 20, 2016. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods; and failed to have no priority violations during the inspection.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

81) Order Type and Number: Consent Order 2017-206-02-028

Order Date: September 15, 2017
Individual/Entity: Takosushi III
Facility: Takosushi III

<u>Location</u>: 34 South Main Street

Greenville, SC 29601

Mailing Address:SameCounty:GreenvillePrevious Orders:None

<u>Permit Number</u>: 23-206-09364

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Takosushi III (Individual/Entity) is a restaurant located in Greenville, South Carolina. The Department conducted inspections on November 7, 2016, August 8, 2017, and August 15, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

82) Order Type and Number: Consent Order 2017-206-03-020

Order Date:September 15, 2017Individual/Entity:Gus' House of PizzaFacility:Gus' House of PizzaLocation:605 South Main Street

Lancaster, SC 29720

Mailing Address: P.O. Box 306

Kershaw, SC 29067

County: Lancaster

<u>Previous Orders</u>: 2013-206-04-002 (\$750.00)

2016-206-03-026 (\$1,200.00)

<u>Permit Number:</u> 29-206-00743

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Gus' House of Pizza (Individual/Entity) is a restaurant located in Lancaster, South Carolina. The Department conducted an inspection on February 13, 2017. The

Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

<u>Action</u>: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of one thousand dollars **(\$1,000.00)**.

83) Order Type and Number: Consent Order 2017-206-06-035

Order Date:September 15, 2017Individual/Entity:Waffle House #1892Facility:Waffle House #1892

<u>Location</u>: 2811 South Kings Highway

Myrtle Beach, SC 29577

Mailing Address: Same County: Horry

<u>Previous Orders</u>: 2016-206-06-042 (\$800.00)

<u>Permit Number</u>: 26-206-11613

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Waffle House #1892 (Individual/Entity) is a restaurant located in Myrtle Beach, South Carolina. The Department conducted an inspection on March 21, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of one thousand dollars (\$1,000.00).

84) Order Type and Number: Consent Order 2017-206-07-022

Order Date: September 15, 2017
Individual/Entity: Meeting Street Inn
Facility: Meeting Street Inn
Location: 173 Meeting Street
Charleston, SC 29401

Mailing Address:SameCounty:CharlestonPrevious Orders:None

<u>Permit Number:</u> 10-206-09276

Violations Cited: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Meeting Street Inn (Individual/Entity) is a restaurant located in Charleston, South Carolina. The Department conducted inspections on August 4, 2016, August 15, 2016, July 11, 2017, and July 21, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that the handwashing sinks were accessible at all times.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

85) Order Type and Number: Consent Order 2016-206-03-101

Order Date: September 18, 2017

Individual/Entity:Fat BoyFacility:Fat Boy

<u>Location</u>: 3260 Augusta Road

West Columbia, SC 29170

<u>Mailing Address</u>: 4854 Landrum Drive

Columbia, SC 29206

<u>County</u>: Lexington <u>Previous Orders</u>: None

<u>Permit Number</u>: 32-206-02061

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Fat Boy (Individual/Entity) is a restaurant located in West Columbia, South Carolina. The Department conducted inspections on October 1, 2015, August 24, 2016, and August 31, 2016. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of seven hundred fifty dollars (\$750.00).

86) Order Type and Number: Consent Order 2016-206-03-126

Order Date:September 18, 2017Individual/Entity:Amber Buffet & HibachiFacility:Amber Buffet & HibachiLocation:2275 Dave Lyle Boulevard

Rock Hill, SC 29730

Mailing Address: Same County: York

Previous Orders: 2015-206-03-103 (\$800.00)

<u>Permit Number:</u> 46-206-03211

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Amber Buffet & Hibachi (Individual/Entity) is a restaurant located in Rock Hill, South Carolina. The Department conducted inspections on August 3, 2016, December 6, 2016, and December 16, 2016. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods; and failed to have no priority violations during the inspection.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of two thousand dollars **(\$2,000.00)**.

87) <u>Order Type and Number</u>: Consent Order 2017-206-03-027

Order Date:September 18, 2017Individual/Entity:Buddy's on Wilson #2Facility:Buddy's on Wilson #2Location:2453 Wilson Road

Newberry, SC 29108

<u>Mailing Address</u>: Same <u>County</u>: Newberry

<u>Previous Orders</u>: 2016-206-03-113 (\$800.00)

<u>Permit Number</u>: 36-206-01104

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Buddy's on Wilson #2 (Individual/Entity) is a restaurant located in Newberry, South Carolina. The Department conducted an inspection on July 26, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the premises free of insects, rodents, and other pests.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of five hundred dollars (\$500.00).

88) <u>Order Type and Number</u>: Consent Order 2016-206-07-084

Order Date: September 19, 2017

Individual/Entity:Sbarro #688Facility:Sbarro #688

<u>Location</u>: 2150 Northwoods Boulevard, FC-2

North Charleston, SC 29406

Mailing Address: 401 Broadhollow Road

Melville, NY 11747

<u>County</u>: Charleston

<u>Previous Orders</u>: None

<u>Permit Number:</u> 10-206-02304

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Sbarro #688 (Individual/Entity) is a restaurant located in North Charleston, South Carolina. The Department conducted inspections on September 15, 2016, September

23, 2016, and October 3, 2016. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

89) <u>Order Type and Number</u>: Consent Order 2017-206-01-017

Order Date:September 19, 2017Individual/Entity:Clock of AndersonFacility:Clock of AndersonLocation:105 Centerville Road

Anderson, SC 29624

Mailing Address:SameCounty:Anderson

<u>Previous Orders</u>: 2016-206-01-014 (\$800.00)

<u>Permit Number</u>: 04-206-03635

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Clock of Anderson (Individual/Entity) is a restaurant located in Anderson, South Carolina. The Department conducted an inspection on June 2, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of one thousand, two hundred dollars (\$1,200.00).

90) Order Type and Number: Consent Order 2017-206-02-027

Order Date:September 19, 2017Individual/Entity:Toss Pizza PubFacility:Toss Pizza Pub

<u>Location</u>: 823 South Church Street, Suite B

Greenville, SC 29601

Mailing Address:SameCounty:GreenvillePrevious Orders:None

<u>Permit Number:</u> 23-206-11459

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Toss Pizza Pub (Individual/Entity) is a restaurant located in Greenville, South Carolina. The Department conducted inspections on October 26, 2016, August 9, 2017, and August 16, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

91) Order Type and Number: Consent Order 2017-206-03-023

Order Date:September 21, 2017Individual/Entity:City Tavern of Fort MillFacility:City Tavern of Fort MillLocation:501 Crossroads Plaza

Fort Mill, SC 29708

Mailing Address: Same County: York

<u>Previous Orders</u>: 2016-206-03-086 (\$800.00)

<u>Permit Number</u>: 46-206-03285

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: City Tavern of Fort Mill (Individual/Entity) is a restaurant located in Fort Mill, South Carolina. The Department conducted an inspection on May 25, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of one thousand dollars (\$1,000.00).

92) Order Type and Number: Consent Order 2016-206-03-122

Order Date: September 25, 2017

Individual/Entity:Subway #35857 at Wal-MartFacility:Subway #35857 at Wal-MartLocation:1121 Stonecrest Boulevard

Tega Cay, SC 29708

Mailing Address: 10013 Strike the Gold Lane

Waxhaw, NC 28173

<u>County</u>: York <u>Previous Orders</u>: None

Permit Number: 46-206-02396

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Subway #35857 at Wal-Mart (Individual/Entity) is a restaurant located in Tega Cay, South Carolina. The Department conducted inspections on September 30, 2015, September 26, 2016, October 6, 2016, and October 14, 2016. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: the facility failed to meet the lighting intensity as measured by foot candles throughout specific areas of the facility. The regulation has specific requirements for lighting intensity based on food preparation or cleaning procedures that are done in certain areas throughout the facility.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of four hundred dollars (\$400.00).

93) Order Type and Number: Consent Order 2016-206-04-034

Order Date:September 25, 2017Individual/Entity:Pamplico GrillFacility:Pamplico Grill

<u>Location</u>: 721 South Walnut Street

Pamplico, SC 29583

Mailing Address:SameCounty:FlorencePrevious Orders:None

<u>Permit Number</u>: 21-206-02551

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Pamplico Grill (Individual/Entity) is a restaurant located in Pamplico, South Carolina. The Department conducted inspections on December 29, 2015, August 2, 2016, and August 16, 2016. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of five hundred fifty dollars (\$550.00).

94) Order Type and Number: Consent Order 2016-206-06-156

Order Date:September 25, 2017Individual/Entity:Senor Willies Taco ShackFacility:Senor Willies Taco Shack

Location: 206 Main Street

North Myrtle Beach, SC 29582

Mailing Address: P.O. Box 154

North Myrtle Beach, SC 29597

<u>County</u>: Horry <u>Previous Orders</u>: None

Permit Number: 26-206-12363

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Senor Willies Taco Shack (Individual/Entity) is a restaurant located in North Myrtle Beach, South Carolina. The Department conducted inspections on May 4, 2016, August 19, 2016, and April 28, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of five hundred fifty dollars (\$550.00).

95) Order Type and Number: Consent Order 2017-206-02-011

Order Date: September 25, 2017

Individual/Entity:Red BowlFacility:Red Bowl

<u>Location</u>: 205 Blackstock Road, Suite 590

Spartanburg, SC 29305

Mailing Address: 205 Hyde Park

Fort Mill, SC 29708

<u>County</u>: Spartanburg

<u>Previous Orders</u>: None

<u>Permit Number:</u> 42-206-05939

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Red Bowl (Individual/Entity) is a restaurant located in Spartanburg, South Carolina. The Department conducted inspections on March 2, 2016, December 2, 2016, and February 22, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

96) Order Type and Number: Consent Order 2017-206-02-029

Order Date: September 25, 2017

<u>Individual/Entity</u>: **Bex Café**Facility: Bex Café

Location: 820 South Main Street

Greenville, SC 29601

Mailing Address:SameCounty:GreenvillePrevious Orders:None

<u>Permit Number:</u> 23-206-11260

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Bex Café (Individual/Entity) is a restaurant located in Greenville, South Carolina. The Department conducted inspections on November 20, 2015, September 21, 2016, and June 12, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the proper sanitization concentration in a chemical sanitizer used in a manual or mechanical operation during contact times.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

97) Order Type and Number: Consent Order 2017-206-03-033

Order Date:September 25, 2017Individual/Entity:Circle K #5140Facility:Circle K #5140

<u>Location</u>: 2202 Bush River Road

Columbia, SC 29210

Mailing Address: 2440 Whitehall Park Drive, #800

Charlotte, NC 28273

<u>County</u>: Lexington <u>Previous Orders</u>: None

<u>Permit Number</u>: 32-206-02752

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Circle K #5140 (Individual/Entity) is a convenience store located in Columbia, South Carolina. The Department conducted inspections on March 2, 2017, March 9, 2017, and March 16, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

98) Order Type and Number: Consent Order 2017-206-03-056

Order Date: September 25, 2017
Individual/Entity: Old York Seafood
Facility: Old York Seafood
Location: 1880 Old York Road
York, SC 29745

Mailing Address:SameCounty:YorkPrevious Orders:None

<u>Permit Number</u>: 46-206-03435

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Old York Seafood (Individual/Entity) is a restaurant located in York, South Carolina. The Department conducted inspections on February 9, 2017, April 6, 2017, and April 13, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods; and failed to have no priority violations during the inspection.

<u>Action</u>: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

99) Order Type and Number: Consent Order 2017-206-03-061

Order Date: September 25, 2017

Individual/Entity:Villa Fresh Italian KitchenFacility:Villa Fresh Italian KitchenLocation:100 Columbiana Circle

Columbia, SC 29212

Mailing Address: 25 Washington Street

Morristown, NJ 07960

<u>County</u>: Lexington <u>Previous Orders</u>: None

<u>Permit Number</u>: 32-206-06381

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Villa Fresh Italian Kitchen (Individual/Entity) is a restaurant located in Columbia, South Carolina. The Department conducted inspections on May 16, 2016, May 11, 2017, and May 19, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

100) Order Type and Number: Consent Order 2017-206-06-021

Order Date:September 25, 2017Individual/Entity:Pop Pop's Pit BBQFacility:Pop Pop's Pit BBQLocation:8724 Highway 707

Myrtle Beach, SC 29588

Mailing Address:SameCounty:HorryPrevious Orders:None

<u>Permit Number</u>: 26-206-12851

Violations Cited: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Pop Pop's Pit BBQ (Individual/Entity) is a restaurant located in Myrtle Beach, South Carolina. The Department conducted inspections on February 10, 2016, September 20, 2016, and March 21, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to cook, cool, and reheat for hot holding to a

temperature of at least 165°F (74°C) for fifteen seconds, for all parts of Time/Temperature Control for Safety Foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

101) Order Type and Number: Consent Order 2017-206-06-048

Order Date:September 25, 2017Individual/Entity:Clubhouse NMBFacility:Clubhouse NMBLocation:77 Highway 17 South

North Myrtle Beach, SC 29582

Mailing Address: Same County: Horry

<u>Previous Orders</u>: 2016-206-06-011 (\$800.00)

<u>Permit Number</u>: 26-206-12847

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Clubhouse NMB (Individual/Entity) is a restaurant located in North Myrtle Beach, South Carolina. The Department conducted an inspection on July 12, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of one thousand dollars (\$1,000.00).

102) Order Type and Number: Consent Order 2017-206-07-018

Order Date:September 25, 2017Individual/Entity:Captain D's #9486Facility:Captain D's #9486Location:112 North Highway 52

Moncks Corner, SC 29461

Mailing Address:SameCounty:BerkeleyPrevious Orders:None

<u>Permit Number</u>: 08-206-00641

<u>Violations Cited</u>: S.C. Code Ann. Regs. 61-25

<u>Summary</u>: Captain D's #9486 (Individual/Entity) is a restaurant located in Moncks Corner, South Carolina. The Department conducted inspections on August 11, 2016, June 29, 2017, and July 5, 2017. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25; and pay a civil penalty in the amount of eight hundred dollars (\$800.00).

^{*} Unless otherwise specified, "Previous Orders" as listed in this report include orders issued by Environmental Affairs Programs within the last five (5) years.

SUMMARY SHEET SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

November 9, 2017

(X) ACTION/DECISION

() INFORMATION

I. TITLE: Request for a nine month extension by the Board of Certificate of Need (CON) SC-15-26 issued to Medical University Hospital Authority d/b/a Medical University of South Carolina (MUSC) for renovation of existing facility for the addition of fifty-two (52) acute hospital beds for a total of six hundred fifty-six (656) acute hospital beds, the purchase of a Siemens Artis Q Biplane, and the renovation of the existing inpatient pharmacy.

II. SUBJECT: MUSC requests Board approval for extension of CON SC-15-26.

III. FACTS: CON SC-15-26 was issued to MUSC on June 30, 2015 for the referenced project. The original CON had an expiration date of June 30, 2016. MUSC requested a first staff extension of the CON on May 19, 2016, which was more than 30 days prior to expiration. MUSC received CON SC-15-26-EXT-1 on June 8, 2016, and it was valid until March 30, 2017, a period of nine months from original expiration of the CON. MUSC requested a second staff extension of the CON on February 6, 2017, which was more than 30 days prior to expiration. MUSC received CON SC-15-26-EXT-2 on March 6, 2017, and it will expire on January 1, 2018. In accordance with R. 61-15, Section 601, MUSC submitted a third extension request to the Department on August 4, 2017, which is more than 90 days prior to expiration.

IV. ANALYSIS: Department staff have reviewed all relevant information concerning this third extension request and find that construction timelines beyond the control of MUSC have contributed to the need for further extension of CON SC-15-26. While parts of the project have been implemented in accordance with the CON, there are several approved beds which cannot be implemented until such time as MUSC's new children's hospital and women's pavilion is complete and licensed. Staff expect that additional extensions by the Board will be necessary until such time as that larger project is complete in late 2019.

V. RECOMMENDATION: Department staff recommend the Board finds that MUSC has demonstrated substantial progress on this project and approve this extension request.

Approved by:

Shelly Bezanson Kelly

Director of Health Regulation

Attachments:

A) CON SC-15-26

B) Letter granting first extension of CON

C) Letter granting second extension of CON

D) Letter requesting third extension of CON

South Carolina Department of Health and Environmental Control



SC-15-26

IS HEREBY ISSUED TO FACILITY: MUSC Ashley River Tower, MUSC Children's Hospital and

Women's Pavilion, MUSC University Hospital

FACILITY LOCATION: Charleston, South Carolina

Charleston County

LICENSEE: Medical University Hospital Authority d/b/a Medical University of South Carolina Children's

Hospital and Women's Pavilion and Medical University of South Carolina Ashley River Tower

AGENT: Thomas L. Stephenson, Esq., Chairman, Children's Hospital and Women's Pavilion

FOR: Renovation of existing facility for the addition of fifty-two (52) acute hospital beds for a total of six hundred fifty-six (656) acute hospital beds, purchase of a Siemens Artis Q Biplane; and renovation of the existing inpatient pharmacy.

TOTAL PROJECT COST: \$9,178,112.

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the "State Certification of Need and Health Facility Licensure Act," S.C. Code Ann. 44-7-110 et seq. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until June 30, 2016 which is a period of twelve (12) months from the date of issuance unless the applicant receives an extension from the Department in accordance with applicable regulations.

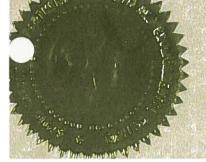
Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and

Environmental Control this 30th day of June, 2015.

Robert B. (Sam) Phillips, Esq.

Director, Certificate of Need Program

Bureau of Health Facilities and Services Development







Catherine E. Heigel, Director

Promoting and protecting the health of the public and the congruencent

June 8, 2016

VIA EMAIL AND CERTIFIED MAIL

Sarah Bacik, MHA
Chief Strategy and Business Development Officer
MUSC Health
261 Calhoun Street, Suite 100
Cannon Park Place, MSC 566
Charleston, SC 29425-3320

Article #: 92148969009997901405002030

Re:

Request for an Extension of Certificate of Need No. SC-15-26

Project: Renovation of existing facility for the addition of fifty-two (52) acute hospital beds for a total of six hundred fifty-six (656) acute hospital beds, purchase of a Siemens Artis Q Biplane; and renovation of the existing inpatient pharmacy.

Charleston, South Carolina

Dear Ms. Bacik:

The South Carolina Department of Health and Environmental Control ("Department") has reviewed your request for an extension of the above referenced Certificate of Need ("Certificate" or "CON"). A Certificate is valid for one year from the date of issuance. SC Code § 44-7-230(D). If a project is not completed before the expiration of that year, or if progress on the project does not comply with the timetable set forth in the CON application, then the Department may revoke the Certificate. The holder of a CON may apply to the Department for an extension of the Certificate's expiration period pursuant to S.C. Code Regs. 61-15 sections 601 through 603. Initially, Department staff may grant up to two extensions of as long as nine months apiece upon a proper showing that substantial progress has been made in implementing the project. Subsequent extensions may only be granted by the Department's Board. SC Code § 44-7-230(D).

Based on the material you provided in support of your request, it is the decision of the Department to **grant you** a nine (9) month initial extension for Certificate No. SC-15-26. The Department's decision is based on the following findings:

- You have demonstrated that circumstances beyond the control of the applicant have prevented compliance with the Project's approved timetable, and
- You have provided the Department with reasonable assurance that the Project will be under construction or implemented within the requested extension period.

A copy of the Department's Guide to Board Review is enclosed for your convenience. Should you require further information, please contact me at (803) 545-3652.

Letter to Sarah Bacik June 8, 2016 Page 2

Sincerely,

Louis Eubank

Director, Certificate of Need Program

Enclosures: Guide to Board Review.

CON SC-15-26-EXT-1

Cc: Caroline Cotter (email)

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

The decision of the South Carolina Department of Health and Environmental Control (Department) becomes the final agency decision fifteen (15) calendar days after notice of the decision has been mailed to the applicant, permittee, licensee and affected persons who have requested in writing to be notified, unless a written request for final review accompanied by a filing fee in the amount of \$100 is filed with Department by the applicant, permittee, licensee or affected person.

Applicants, permittees, licensees, and affected parties are encouraged to engage in mediation or settlement discussions during the final review process.

If the Board declines in writing to schedule a final review conference, the Department's decision becomes the final agency decision and an applicant, permittee, licensee, or affected person may request a contested case hearing before the Administrative Law Court within thirty (30) calendar days after notice is mailed that the Board declined to hold a final review conference. In matters pertaining to decisions under the South Carolina Mining Act, appeals should be made to the South Carolina Mining Council.

I. Filing of Request for Final Review

- 1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars (\$100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
- 2. RFRs shall be in writing and should include, at a minimum, the following information:
 - The grounds for amending, modifying, or rescinding the staff decision:
 - a statement of any significant issues or factors the Board should consider in deciding how to handle the matter;
 - the relief requested;
 - a copy of the decision for which review is requested; and
 - mailing address, email address, if applicable, and phone number(s) at which the requestor can be contacted.
- 3. RFRs should be filed in person or by mail at the following address:

South Carolina Board of Health and Environmental Control

Attention: Clerk of the Board

2600 Bull Street

Columbia, South Carolina 29201

Alternatively, RFR's may be filed with the Clerk by facsimile (803-898-3393) or by electronic mail (boardclerk@dhec.sc.gov).

- 4. The filing fee may be paid by cash, check or credit card and must be received by the 15th day.
- 5. If there is any perceived discrepancy in compliance with this RFR filing procedure, the Clerk should consult with the Chairman or, if the Chairman is unavailable, the Vice-Chairman. The Chairman or the Vice-Chairman will determine whether the RFR is timely and properly filed and direct the Clerk to (1) process the RFR for consideration by the Board or (2) return the RFR and filing fee to the requestor with a cover letter explaining why the RFR was not timely or properly filed. Processing an RFR for consideration by the Board shall not be interpreted as a waiver of any claim or defense by the agency in subsequent proceedings concerning the RFR.
- 6. If the RFR will be processed for Board consideration, the Clerk will send an Acknowledgement of RFR to the Requestor and the applicant, permittee, or licensee, if other than the Requestor. All personal and financial identifying information will be redacted from the RFR and accompanying documentation before the RFR is released to the Board, Department staff or the public.
- 7. If an RFR pertains to an emergency order, the Clerk will, upon receipt, immediately provide a copy of the RFR to all Board members. The Chairman, or in his or her absence, the Vice-Chairman shall based on the circumstances, decide whether to refer the RFR to the RFR Committee for expedited review or to decline in writing to schedule a Final Review Conference. If the Chairman or Vice-Chairman determines review by the RFR Committee is appropriate, the Clerk will forward a copy of the RFR to Department staff and Office of General Counsel. A Department response and RFR Committee review will be provided on an expedited schedule defined by the Chairman or Vice-Chairman.
- 8. The Clerk will email the RFR to staff and Office of General Counsel and request a Department Response within eight (8) working days. Upon receipt of the Department Response, the Clerk will forward the RFR and Department Response to all Board members for review, and all Board members will confirm receipt of the RFR to the Clerk by email. If a Board member does not confirm receipt of the RFR within a twenty-four (24) hour period, the Clerk will contact the Board member and confirm receipt. If a Board member believes the RFR should be considered by the RFR Committee, he or she will

respond to the Clerk's email within forty-eight (48) hours and will request further review. If no Board member requests further review of the RFR within the forty-eight (48) hour period, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Final Review Conference. Contested case guidance will be included within the letter.

NOTE: If the time periods described above end on a weekend or State holiday, the time is automatically extended to 5:00 p.m. on the next business day.

- 9. If the RFR is to be considered by the RFR Committee, the Clerk will notify the Presiding Member of the RFR Committee and the Chairman that further review is requested by the Board. RFR Committee meetings are open to the public and will be public noticed at least 24 hours in advance.
- 10. Following RFR Committee or Board consideration of the RFR, if it is determined no Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Conference. Contested case guidance will be included within the letter.

II. Final Review Conference Scheduling

- 1. If a Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, informing the Requestor of the determination.
- 2. The Clerk will request Department staff provide the Administrative Record.
- 3. The Clerk will send Notice of Final Review Conference to the parties at least ten (10) days before the Conference. The Conference will be publically noticed and should:
 - include the place, date and time of the Conference;
 - state the presentation times allowed in the Conference;
 - state evidence may be presented at the Conference;
 - if the conference will be held by committee, include a copy of the Chairman's order appointing the committee; and
 - inform the Requestor of his or her right to request a transcript of the proceedings of the Conference prepared at Requestor's expense.
- 4. If a party requests a transcript of the proceedings of the Conference and agrees to pay all related costs in writing, including costs for the transcript, the Clerk will schedule a court reporter for the Conference.

III. Final Review Conference and Decision

- 1. The order of presentation in the Conference will, subject to the presiding officer's discretion, be as follows:
 - Department staff will provide an overview of the staff decision and the applicable law to include [10 minutes]:
 - Type of decision (permit, enforcement, etc.) and description of the program.
 - Parties
 - Description of facility/site
 - Applicable statutes and regulations
 - Decision and materials relied upon in the administrative record to support the staff decision.
 - Requestor(s) will state the reasons for protesting the staff decision and may provide evidence to support amending, modifying, or rescinding the staff decision. [15 minutes] NOTE: The burden of proof is on the Requestor(s)
 - Rebuttal by Department staff [15 minutes]
 - Rebuttal by Requestor(s) [10 minutes]
 - Note: Times noted in brackets are for information only and are superseded by times stated in the Notice of Final Review Conference or by the presiding officer.
- 2. Parties may present evidence during the conference; however, the rules of evidence do not apply.
- 3. At any time during the conference, the officers conducting the Conference may request additional information and may question the Requestor, the staff, and anyone else providing information at the Conference.
- 4. The presiding officer, in his or her sole discretion, may allow additional time for presentations and may impose time limits on the Conference.
- 5. All Conferences are open to the public.
- 6. The officers may deliberate in closed session.
- 7. The officers may announce the decision at the conclusion of the Conference or it may be reserved for consideration.
- 8. The Clerk will mail the written final agency decision (FAD) to parties within 30 days after the Conference. The written decision must explain the basis for the decision and inform the parties of their right to request a contested case hearing before the Administrative Law Court or in matters pertaining to decisions under the South Carolina Mining Act, to request a hearing before the South Carolina Mining Council. The FAD will be sent by certified mail, return receipt requested.
- 9. Communications may also be sent by electronic mail, in addition to the forms stated herein, when electronic mail addresses are provided to the Clerk.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

South Carolina Department of Health and Environmental Control



SC-15-26-EXT-1

IS HEREBY ISSUED TO FACILITY: MUSC Ashley River Tower, MUSC Children's Hospital and

Women's Pavilion, MUSC University Hospital

FACILITY LOCATION: Charleston, South Carolina

Charleston County

LICENSEE: Medical University Hospital Authority d/b/a Medical University of South Carolina Children's

Hospital and Women's Pavilion and Medical University of South Carolina Ashley River Tower

AGENT: Thomas L. Stephenson, Esq., Chairman, Children's Hospital and Women's Pavilion

FOR: Renovation of existing facility for the addition of fifty-two (52) acute hospital beds for a total of six hundred fifty-six (656) acute hospital beds, purchase of a Siemens Artis Q Biplane; and renovation of the existing inpatient pharmacy.

TOTAL PROJECT COST: \$9,178,112.

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the "State Certification of Need and Health Facility Licensure Act," S.C. Code Ann. 44-7-110 et seq. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until March 30, 2017 which is a period of nine (9) months from the date of issuance unless the applicant receives an additional extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this 8th day of June, 2016.

Louis Eubank

Director, Certificate of Need Program

Bureau of Health Facilities and Services Development









March 6, 2017

VIA EMAIL AND CERTIFIED MAIL

Sarah Bacik, MHA Chief Strategy and Business Development Officer MUSC Health 261 Calhoun Street, Suite 100 Cannon Park Place, MSC 566 Charleston, SC 29425-3320

Request for an Extension of Certificate of Need No. SC-15-26

Project: Renovation of existing facility for the addition of fifty-two (52) acute hospital beds for a total of six hundred fifty-six (656) acute hospital beds, purchase of a Siemens Artis Q Biplane; and renovation of the existing

inpatient pharmacy.

Charleston, South Carolina

Dear Ms. Bacik:

The South Carolina Department of Health and Environmental Control ("Department") has reviewed your request for an extension of the above referenced Certificate of Need ("Certificate" or "CON"). A Certificate is valid for one year from the date of issuance. SC Code § 44-7-230(D). If a project is not completed before the expiration of that year, or if progress on the project does not comply with the timetable set forth in the CON application, then the Department may revoke the Certificate. The holder of a CON may apply to the Department for an extension of the Certificate's expiration period pursuant to S.C. Code Regs. 61-15 sections 601 through 603. Initially, Department staff may grant up to two extensions of as long as nine months apiece upon a proper showing that substantial progress has been made in implementing the project. Subsequent extensions may only be granted by the Department's Board. SC Code § 44-7-230(D).

Based on the material you provided in support of your request, it is the decision of the Department to grant you a second nine (9) month extension for Certificate No. SC-15-26. The Department's decision is based on the following findings:

- You have demonstrated that circumstances beyond the control of the applicant have prevented compliance with the Project's approved timetable, and
- You have provided the Department with reasonable assurance that the Project will be under construction or implemented within the requested extension period.

A copy of the Department's Guide to Board Review is enclosed for your convenience. Should you require further information, please contact me at (803) 545-3652.

Sincerely,

Louis Eubank

Director, Certificate of Need Program

Enclosures: Guide to Board Review

CON SC-15-26-EXT-2

Cc: Caroline Cotter (email)

South Carolina Board of Health and Environmental Control

Guide to Board Review

Pursuant to S.C. Code Ann. § 44-1-60

The decision of the South Carolina Department of Health and Environmental Control (Department) becomes the final agency decision fifteen (15) calendar days after notice of the decision has been mailed to the applicant, permittee, licensee and affected persons who have requested in writing to be notified, unless a written request for final review accompanied by a filing fee in the amount of \$100 is filed with Department by the applicant, permittee, licensee or affected person.

Applicants, permittees, licensees, and affected parties are encouraged to engage in mediation or settlement discussions during the final review process.

If the Board declines in writing to schedule a final review conference, the Department's decision becomes the final agency decision and an applicant, permittee, licensee, or affected person may request a contested case hearing before the Administrative Law Court within thirty (30) calendar days after notice is mailed that the Board declined to hold a final review conference. In matters pertaining to decisions under the South Carolina Mining Act, appeals should be made to the South Carolina Mining Council.

I. Filing of Request for Final Review

- 1. A written Request for Final Review (RFR) and the required filing fee of one hundred dollars (\$100) must be received by Clerk of the Board within fifteen (15) calendar days after notice of the staff decision has been mailed to the applicant, permittee, licensee, or affected persons. If the 15th day occurs on a weekend or State holiday, the RFR must be received by the Clerk on the next working day. RFRs will not be accepted after 5:00 p.m.
- 2. RFRs shall be in writing and should include, at a minimum, the following information:
 - The grounds for amending, modifying, or rescinding the staff decision;
 - a statement of any significant issues or factors the Board should consider in deciding how to handle the matter;
 - the relief requested;
 - a copy of the decision for which review is requested; and
 - mailing address, email address, if applicable, and phone number(s) at which the requestor can be contacted.
- 3. RFRs should be filed in person or by mail at the following address:

South Carolina Board of Health and Environmental Control

Attention: Clerk of the Board

2600 Bull Street

Columbia, South Carolina 29201

Alternatively, RFR's may be filed with the Clerk by facsimile (803-898-3393) or by electronic mail (boardclerk@dhec.sc.gov).

- 4. The filing fee may be paid by cash, check or credit card and must be received by the 15th day.
- 5. If there is any perceived discrepancy in compliance with this RFR filing procedure, the Clerk should consult with the Chairman or, if the Chairman is unavailable, the Vice-Chairman. The Chairman or the Vice-Chairman will determine whether the RFR is timely and properly filed and direct the Clerk to (1) process the RFR for consideration by the Board or (2) return the RFR and filing fee to the requestor with a cover letter explaining why the RFR was not timely or properly filed. Processing an RFR for consideration by the Board shall not be interpreted as a waiver of any claim or defense by the agency in subsequent proceedings concerning the RFR.
- 6. If the RFR will be processed for Board consideration, the Clerk will send an Acknowledgement of RFR to the Requestor and the applicant, permittee, or licensee, if other than the Requestor. All personal and financial identifying information will be redacted from the RFR and accompanying documentation before the RFR is released to the Board, Department staff or the public.
- 7. If an RFR pertains to an emergency order, the Clerk will, upon receipt, immediately provide a copy of the RFR to all Board members. The Chairman, or in his or her absence, the Vice-Chairman shall based on the circumstances, decide whether to refer the RFR to the RFR Committee for expedited review or to decline in writing to schedule a Final Review Conference. If the Chairman or Vice-Chairman determines review by the RFR Committee is appropriate, the Clerk will forward a copy of the RFR to Department staff and Office of General Counsel. A Department response and RFR Committee review will be provided on an expedited schedule defined by the Chairman or Vice-Chairman.
- 8. The Clerk will email the RFR to staff and Office of General Counsel and request a Department Response within eight (8) working days. Upon receipt of the Department Response, the Clerk will forward the RFR and Department Response to all Board members for review, and all Board members will confirm receipt of the RFR to the Clerk by email. If a Board member does not confirm receipt of the RFR within a twenty-four (24) hour period, the Clerk will contact the Board member and confirm receipt. If a Board member believes the RFR should be considered by the RFR Committee, he or she will

respond to the Clerk's email within forty-eight (48) hours and will request further review. If no Board member requests further review of the RFR within the forty-eight (48) hour period, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Final Review Conference. Contested case guidance will be included within the letter.

NOTE: If the time periods described above end on a weekend or State holiday, the time is automatically extended to 5:00 p.m. on the next business day.

- 9. If the RFR is to be considered by the RFR Committee, the Clerk will notify the Presiding Member of the RFR Committee and the Chairman that further review is requested by the Board. RFR Committee meetings are open to the public and will be public noticed at least 24 hours in advance.
- 10. Following RFR Committee or Board consideration of the RFR, if it is determined no Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, stating the Board will not hold a Conference. Contested case guidance will be included within the letter.

II. Final Review Conference Scheduling

- 1. If a Conference will be held, the Clerk will send a letter by certified mail to the Requestor, with copy by regular mail to the applicant, permittee, or licensee, if not the Requestor, informing the Requestor of the determination.
- 2. The Clerk will request Department staff provide the Administrative Record.
- 3. The Clerk will send Notice of Final Review Conference to the parties at least ten (10) days before the Conference. The Conference will be publically noticed and should:
 - include the place, date and time of the Conference;
 - state the presentation times allowed in the Conference;
 - state evidence may be presented at the Conference;
 - if the conference will be held by committee, include a copy of the Chairman's order appointing the committee; and
 - inform the Requestor of his or her right to request a transcript of the proceedings of the Conference prepared at Requestor's expense.
- 4. If a party requests a transcript of the proceedings of the Conference and agrees to pay all related costs in writing, including costs for the transcript, the Clerk will schedule a court reporter for the Conference.

III. Final Review Conference and Decision

- 1. The order of presentation in the Conference will, subject to the presiding officer's discretion, be as follows:
 - Department staff will provide an overview of the staff decision and the applicable law to include [10 minutes]:
 - Type of decision (permit, enforcement, etc.) and description of the program.
 - Parties
 - Description of facility/site
 - Applicable statutes and regulations
 - Decision and materials relied upon in the administrative record to support the staff decision.
 - Requestor(s) will state the reasons for protesting the staff decision and may provide evidence to support amending, modifying, or rescinding the staff decision. [15 minutes] NOTE: The burden of proof is on the Requestor(s)
 - Rebuttal by Department staff [15 minutes]
 - Rebuttal by Requestor(s) [10 minutes]
 - Note: Times noted in brackets are for information only and are superseded by times stated in the Notice of Final Review Conference or by the presiding officer.
- 2. Parties may present evidence during the conference; however, the rules of evidence do not apply.
- 3. At any time during the conference, the officers conducting the Conference may request additional information and may question the Requestor, the staff, and anyone else providing information at the Conference.
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- 9. Communications may also be sent by electronic mail, in addition to the forms stated herein, when electronic mail addresses are provided to the Clerk.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

South Carolina Department of Health and Environmental Control



SC-15-26-EXT-2

IS HEREBY ISSUED TO FACILITY: MUSC Ashley River Tower, MUSC Children's Hospital and

Women's Pavilion, MUSC University Hospital

FACILITY LOCATION: Charleston, South Carolina

Charleston County

LICENSEE: Medical University Hospital Authority d/b/a Medical University of South Carolina Children's

Hospital and Women's Pavilion and Medical University of South Carolina Ashley River Tower

AGENT: Thomas L. Stephenson, Esq., Chairman, Children's Hospital and Women's Pavilion

FOR: Renovation of existing facility for the addition of fifty-two (52) acute hospital beds for a total of six hundred fifty-six (656) acute hospital beds, purchase of a Siemens Artis Q Biplane; and renovation of the existing inpatient pharmacy.

TOTAL PROJECT COST: \$9,178,112.

This Certificate is being issued in accordance with the Code of Laws of South Carolina.

In determining the need for this project, the South Carolina Department of Health and Environmental Control has taken into consideration the "Criteria for Project Review" and the South Carolina Health Plan as established in the "State Certification of Need and Health Facility Licensure Act," S.C. Code Ann. 44-7-110 et seq. and Regulation 61-15, "Certification of Need for Health Facilities and Services."

This Certificate of Need is valid until January 1, 2018 which is a period of nine (9) months from the date of prior extension expiration unless the applicant receives an additional extension from the Department in accordance with applicable regulations.

Witness to this Certificate is confirmed by my signature and the seal of the Department of Health and Environmental Control this 6th day of March, 2017.





Louis Eubank
Director, Certificate of Need Program

RE: 52-Bed Expansion 2nd Extension Request

Cotter, Caroline <cotter@musc.edu>

Fri 8/4/2017 2:28 PM

To: Eubank, Louis W. < EUBANKLW@dhec.sc.gov>;

Cc:baciks@musc.edu <baciks@musc.edu>; Murdock, Margaret P. <murdocmp@dhec.sc.gov>; Coninfo, Coninfo <Coninfo@dhec.sc.gov>;

1 attachments (638 KB)

52 Bed CON Extension #3_8.4.17.pdf;

This message was sent securely by MUSC

Hey Louis,

I have attached the third 52 Bed CON Extension (SC-15-26). Please let me know if you have any questions.

Have a great weekend!

Best, Caroline

From: Cotter, Caroline

Sent: Tuesday, August 01, 2017 10:03 AM

To: 'Eubank, Louis W.' < EUBANKLW@dhec.sc.gov > Subject: RE: 52-Bed Expansion 2nd Extension Request

Thank you Louis. We will send you the Extension Request this week.

From: Eubank, Louis W. [mailto:EUBANKLW@dhec.sc.gov]

Sent: Tuesday, August 01, 2017 9:55 AM **To:** Cotter, Caroline <cotter@musc.edu>

Subject: Re: 52-Bed Expansion 2nd Extension Request

Hi Caroline,

Lisa is out of the office on vacation this week and next. The extension request, I believe, is presented to the Board by staff and we request their approval. So, if you could, please prepare the extension request in detail and forward to me just so there is no question about compliance with the Reg. timeline. I will work with Lisa once she returns to get on the Board agenda and I'll make sure you are looped in to that process.

Hope you're having a great week!

- Louis

Louis Eubank, Chief
Bureau of Healthcare Planning and Construction
S.C. Dept. of Health & Environmental Control

Office: (803) 545-3652

Mobile: (803) 730-0523

Connect: www.scdhec.gov Facebook Twitter

This email is intended for the use of the individual or entity to which it is addressed and may contain information which is privileged and confidential. If the reader of this email is not the intended recipient, you are hereby notified that any disclosure, distribution, or copying of this information is strictly prohibited. If you received this email in error please notify the sender immediately by reply.

From: Cotter, Caroline < cotter@musc.edu > Sent: Monday, July 31, 2017 3:08:10 PM

To: Eubank, Louis W. **Cc:** Murdock, Margaret P.

Subject: RE: 52-Bed Expansion 2nd Extension Request

This message was sent securely by MUSC

Louis- My mistake, we have been approved for 2 extensions and the 3rd will need to be approved by the board.

From: Cotter, Caroline

Sent: Monday, July 31, 2017 2:15 PM

To: EUBANKLW@dhec.sc.gov

Cc: Maggie Murdock (murdocmp@dhec.sc.gov) <murdocmp@dhec.sc.gov>

Subject: 52-Bed Expansion 2nd Extension Request

Hey Louis- I am reaching out because I believe Maggie is on vacation this week. We are approaching the deadline to submit the 2nd Extension for the 52-Bed Expansion CON which was 6 months after the 1st extension was approved. You mentioned we would need to submit the request to the DHEC board and work directly with Lisa Longshore.

Do you mind connecting me with Lisa so I can understand what all is required? Should this be filed as a typical extension request?

Thank you, Caroline

Caroline R. Cotter, MHA

The Medical University of South Carolina Senior Planning Associate & Program Manager of Facility Planning cotter@musc.edu 843-792-5603

This message was secured via TLS by MUSC.

This message was secured via TLS by MUSC.



Sarah Bacik, MHA Chief Strategy and Business Development Officer Medical University of South Carolina

261 Calhoun Street, Suite 100 Cannon Park Place, MSC 566 Charleston, SC 29425-3320 Tel 843 792 9917 www.muschealth.com

August 4, 2017

Louis Eubank, Chief Bureau of Healthcare Planning and Construction S.C. Dept. of Health & Environmental Control

RE: MUHA's 52-Bed Expansion Certificate of Need Extension Request 3 (SC-15-26)

Dear Mr. Eubank,

This letter, on behalf of MUHA, is to provide the third extension request on the MUSC 52-Bed Expansion CON (SC-15-26) in accordance with State "Certification of Need and Health Facility Licensure Act," S.C. Code Ann. 44-7-110 et seq. and Regulation 61-15 "Certification of Need for Health Facilities and Services."

First, the fifteen bed expansion included five additional PICU beds on the fifth floor and ten additional pediatric medical surgical beds on floors seven through nine in the future MUSC Shawn Jenkins Children's Hospital and Women's Pavilion (SJCH). MUHA has implemented the construction contract on the CHWP and therefore this portion of the project has been closed out. The estimated completion date is scheduled for October 2019. Updates on this projected will be provided in the quarterly reports.

Second, the ART 7 project included the expansion of four beds in the Ashley River Tower. These four beds were licensed on November 12, 2015 and therefore this project has been closed out. MUHA's renewed bed license is for 713 beds.

Third, the inpatient pharmacy expansion and central materials management relocation in the Ashley River Tower began construction the first week of June 2016 and therefore the project has been closed out. The estimated completion date is scheduled for September 2017.

Fourth, the thirty-three adult medical surgical bed expansion will be constructed in the backfill space of the existing MUSC Children's Hospital, when it is relocated to the Shawn Jenkins Children's Hospital on Courtney Drive. MUSC's master facility planning steering committee conducted a feasibility study to determine the appropriate location of the incremental thirty-three adult inpatient beds within the backfill space. The 2017 State Health Plan has identified the Adult Inpatient bed need for MUSC to be 147 additional beds. The addition of these thirty-three beds will fulfill 22% of this identified need. The beds will be backfilled in a phased approach which will begin when the Shawn Jenkins Children's Hospital is open in October 2019. Updates on this projected will be provided in the quarterly reports.

Finally, the renovation for a Biplane Procedure Room at MUHA is in the planning phase. An alternate location was identified for this equipment as part of the planning phased. As described in the quarterly reports, the Biplane will be added to the backfill of the current Children's Hospital. This was a better alternative than the third floor University Hospital which would disrupt the patient flow to Radiology and as a result was a higher cost option. In

addition, locating the Biplane in the current Children's Hospital will increase patient accessibility to the equipment. The project will be implemented when the space becomes available after the Shawn Jenkins Children's Hospital in October 2019. We plan to maintain the timeline submitted in the CON of approximately ten months after renovation has been initiated. Updates on this projected will be provided in the quarterly reports.

At this time, there have been no additional changes to the project and we request approval from the DHEC Board for an extension of SC-15-26. Please contact me at (843) 843-792-9917 if you have any questions regarding this information.

Sincerely,

Sarah Bacik, MHA

Chief Strategy and Business Development Officer

The Medical University of South Carolina

(x) ACTION/DECISION() INFORMATION

Date: November 9, 2017

To: S.C. Board of Health and Environmental Control

From: Bureau of Health Facilities Licensing

Re: Notice of Proposed Regulation amending Regulation 61-78, Standards for Licensing Hospices.

I. Introduction

The Bureau of Health Facilities Licensing ("Bureau") proposes the attached Notice of Proposed Regulation amending R.61-78, Standards for Licensing Hospices, for publication in the November 24, 2017, South Carolina State Register ("State Register"). Legal authority for this amendment resides in S.C. Code Sections 44-71-10 et seq., which requires the Department of Health and Environmental Control ("Department") to promulgate regulations for standards of care, treatment, health, safety, welfare, and comfort of patients and their families serviced by hospices and for the maintenance and operation of hospices. General Assembly review is required.

II. Facts

- 1. The Bureau proposes amendments to R.61-78 to incorporate newly passed amendments to the Hospice Licensure Act, S.C. Code Sections 44-71-10 et seq. The proposed regulatory amendments include requirements to register multiple locations and updated requirements for medication disposal to comply with the recent statutory changes. The statutory changes also expand Joint Annual Report requirements to outpatient Hospices, however, existing wording of R.61-78 adequately executes those requirements.
- 2. The Department had a Notice of Drafting for the proposed regulatory amendments published in the June 23, 2017, *State Register*. The Department received public comments from two (2) parties by the July 24, 2017, close of the comment period.
- 3. Attachment C presents a summary of public comments received and Department responses.
- 4. The Department completed an internal review of the proposed amendments October 26, 2017. All appropriate Department personnel have reviewed the regulation.
- 5. The Department held a regulation development meeting with Hospice licensees and stakeholders on July 21, 2017. Eleven (11) individuals attended the meeting and gave Department representatives an opportunity to receive input on changes to R.61-78.

III. Request for Approval

The Bureau respectfully requests the Board to grant approval of the attached Notice of Proposed Regulation for publication in the November 24, 2017, *State Register*.

Gwen C. Thompson

Chief

Bureau of Health Facilities Licensing

Shelly Beranson Kelly ID

Director

Health Regulation

Attachments:

- A. Notice of Proposed Regulation
 B. Notice of Drafting published in the June 23, 2017, State Register
 C. Summary of Public Comments and Department Responses

ATTACHMENT A

STATE REGISTER NOTICE OF PROPOSED REGULATION FOR REGULATION 61-78, Standards for Licensing Hospices

November 24, 2017

Document No. _____ **DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**CHAPTER 61

Statutory Authority: 1976 Code Sections 44-71-10 et seg.

61-78. Standards for Licensing Hospices.

Preamble:

The Department of Health and Environmental Control ("Department") proposes amending R.61-78, Standards for Licensing Hospices. The proposed amendments incorporate newly passed amendments to the Hospice Licensure Act, S.C. Code Sections 44-71-10 et seq. The proposed regulatory amendments include requirements to register multiple locations and updated requirements for medication disposal to comply with the recent statutory changes. The statutory changes also expand Joint Annual Report requirements to outpatient Hospices, however, existing wording of R.61-78 adequately executes those requirements. General Assembly review is required.

The Department had a Notice of Drafting published in the State Register on June 23, 2017.

Section-by-Section Discussion of Proposed Amendments:

TABLE OF CONTENTS

The table of contents was updated to reflect amended sections.

Section 61-78.100. DEFINITIONS

The definitions of 100.CC Multiple Location, 100.HH Parent Hospice, and 100.PP Primary Office were added. The remaining definitions were updated to reflect the new codification.

Section 61-78.213. Multiple Locations

New Section 213 was added to delineate the requirements for multiple locations. Section 213.A requires hospices to register multiple locations with the Department prior to establishing, operating, maintaining, or representing as such. Section 213.B requires hospices to file an application for the registration of a multiple location. Section 213.C states that the registration of a multiple location is effective until the expiration of the license of the parent hospice.

Section 61-78.214. Exceptions to Licensing Standards (formerly 61-78.213)

Section 214 (formerly 213) was renumbered to adjust the codification.

Section 61-78.401. General

Section 401 was amended to include multiple locations as being subject to monetary penalties, denial, suspension, or revocation for violations of any statute, rule, or regulation.

Section 61-78.1608. Disposition of Medications

Section 1608.B was amended to refer to patients receiving services in hospice facilities only. Section 1608.C was added to require that upon the death of a patient receiving outpatient services, the hospice shall comply with S.C. Code Section 44-71-85. The remaining subsections were renumbered to adjust the codification.

Section 61-78.2106. Utility Rooms

Sections 2106.A and 2106.B were amended to change work station to nurses' station for clarity and consistency.

Section 61-78.2201. Fire Protection

Section 2201.D was amended to change work station to nurses' station for clarity and consistency.

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons may submit comments on the proposed amendments by writing to Gwen C. Thompson by mail at Bureau of Health Facilities Licensing, South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC 29201; by fax at (803) 545-4212; or by email at Health RegComm@dhec.sc.gov. Interested persons may also submit comments electronically on the Public Comments for Health Regulations page at the following address: http://www.scdhec.gov/Agency/RegulationsAndUpdates/PublicComments/. To be considered, the Department must receive the comment(s) no later than 5:00 p.m. on December 27, 2017, the close of the public comment period.

Interested persons may also make oral and/or submit written comments on the proposed amendments of R.61-78 at a public hearing to be conducted by the Board of Health and Environmental Control at its regularly-scheduled meeting on February 8, 2018. The meeting will commence at 10:00 a.m. in the Board Room, Third floor, Aycock Building of the Department of Health and Environmental Control; 2600 Bull Street; Columbia, South Carolina 29201. The order of presentation for public hearings will appear in the Board's agenda published by the Department twenty-four (24) hours in advance of the meeting at the following address: http://www.scdhec.gov/Agency/docs/AGENDA.PDF. Persons desiring to make comments at the public hearing are asked to limit their statements to five (5) minutes or less and, as a courtesy, may provide written copies of their presentations for the record. Due to admittance procedures at the DHEC Building, all visitors should enter through the Bull Street entrance and register at the front desk.

The DHEC Regulation Development Update (accessible at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/) provides a summary of the proposed amendments, a link to the proposed amendments, and applicable contact information. Interested persons may also obtain a copy of the proposed amendments by contacting Gwen Thompson at the above mailing address or by email at https://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/) provides a summary of the proposed amendments, and applicable contact information. Interested persons may also obtain a copy of the proposed amendments by contacting Gwen Thompson at the above mailing address or by email at Health RegComm@dhec.sc.gov/.

Preliminary Fiscal Impact Statement:

As noted in the Fiscal Impact Statement for House Bill 3132 requested by the Senate Medical Affairs committee, the Department estimates an expenditure impact of eighty-three thousand sixty-three dollars (\$83,063) on the General Fund for at least the first year after promulgation of these amendments.

Statement of Need and Reasonableness:

The following is based on an analysis of the factors listed in 1976 Code Sections 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: R.61-78, Standards for Licensing Hospices.

Purpose: The purpose of these amendments to R.61-78 is to incorporate recent changes to the Hospice Licensure Act, S.C. Code Sections 44-71-10 et seq., enacted by the General Assembly. These amendments include requirements to register multiple locations and new requirements for medication disposal.

Legal Authority: 1976 Code Sections 44-71-10 et seq.

Plan for Implementation: The DHEC Regulation Development Update (accessible at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/) provides a summary of the proposed amendment, a link to this Notice of Proposed Regulation, and applicable contact information. Interested persons may also obtain a copy of this Notice of Proposed Regulation by contacting Gwen C. Thompson at the above address or by email at <a href="https://example.gov/Health-Persons-nation-nat

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

These amendments are necessary to incorporate recent statutory changes to the Hospice Licensure Act. The proposed amendments to R.61-78 enable registration of multiple locations and update medication disposal requirements to the new statutory requirements.

DETERMINATION OF COSTS AND BENEFITS:

As noted in the Fiscal Impact Statement for House Bill 3132 requested by the Senate Medical Affairs committee, the Department estimates an expenditure impact of eighty-three thousand sixty-three dollars (\$83,063) on the General Fund for at least the first year after promulgation of these amendments. Hospice providers will pay a licensure fee of one hundred dollars (\$100) per multiple location, plus fifty dollars (\$50) for each county where the multiple location provides services. Implementation of these amendments benefit the regulated community by executing recent changes to the Hospice Licensure Act.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

The amendments to R.61-78 seek to support the Department's goals relating to protection of public health through the anticipated benefits highlighted above. There is no anticipated effect on the environment.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There is no anticipated detrimental effect on the environment. If the proposed amendments are not implemented, the regulation will be maintained in its current form without realizing the benefits of the recently enacted changes to the Hospice Licensure Act.

Statement of Rationale:

The Department of Health and Environmental Control proposes amending R.61-78, Standards for Licensing Hospices. These amendments are necessary to incorporate recent changes to the Hospice Licensure Act,

S.C. Code Sections 44-71-10 et seq. The proposed amendments to R.61-78 enable registration of multiple locations and update medication disposal requirements to the new statutory requirements.

Text:

Deleted text is stricken New text is underlined.

61-78. Standards for Licensing Hospices.

Revise Section 200 of Table of Contents to read:

SECTION 200 - LICENSE REQUIREMENTS

- 201. Scope of Licensure
- 202. License Application
- 203. Compliance
- 204. Issuance of License
- 205. Licensing Fees
- 206. Late Fee
- 207. License Renewal
- 208. Change of License
- 209. Hospice Name
- 210. Licensed Area
- 211. Licensed Bed Capacity
- 212. Persons Received in Excess of Licensed Bed Capacity
- 213. Multiple Locations

213214. Exceptions to Licensing Standards

Revise Section 61-78.100 to read:

Section 100 - DEFINITIONS

For the purpose of this regulation, the following definitions shall apply:

- A. Administrator. The individual designated by the governing body to be responsible for the day-to-day management of the Hospice and when licensed to provide Inpatient Services, Hospice Facility.
- B. Advanced Practice Registered Nurse. An individual who has Official Recognition as such by the South Carolina Board of Nursing.
- C. Airborne Infection Isolation (AII). A room designed to maintain Airborne Infection Isolation (AII), formerly called a negative pressure isolation room. An Airborne Infection Isolation (AII) room is a single-occupancy patient-care room used to isolate persons with suspected or confirmed infectious tuberculosis (TB) disease. Environmental factors are controlled in Airborne Infection Isolation (AII) rooms to minimize the transmission of infectious agents that are usually spread from person-to-person by droplet nuclei associated with coughing or aerosolization of contaminated fluids. Airborne Infection Isolation (AII) rooms may provide negative pressure in the room (so that air flows under the door gap into the room), an air flow rate of six to twelve (6 to 12) air changes per hour (ACH), and direct exhaust of air from the room to the outside of the building or recirculation of air through a high efficiency particulate air (HEPA) filter.

- D. Architect. An individual currently registered as such by the South Carolina State Board of Architectural Examiners.
- E. Attending Physician. The physician who is identified by the patient as having the most significant role in the determination and delivery of medical care to the patient.
- F. Authorized Healthcare Provider. An individual authorized by law and currently licensed in South Carolina to provide specific care, treatment, or services to patients such as, advanced practice registered nurse, physician assistant.
- G. Consultation. A visit by Department representative(s) to provide information to the licensee in order to facilitate compliance with these regulations.
- H. Controlled Substance. A medication or other substance included in Schedule I, II, III, IV, and V of the Federal Controlled Substances Act and the South Carolina Controlled Substances Act.
- I. Counseling Services. Counseling includes bereavement counseling, as well as dietary, spiritual, and any other counseling services provided to the individual and family or responsible party.
 - J. Department. The South Carolina Department of Health and Environmental Control (DHEC).
- K. Dietitian. A person who is registered by the Commission on Dietetic Registration and licensed by the South Carolina Department of Labor, Licensing and Regulation.
- L. Dietary Counseling. Education and interventions provided to the patient and family regarding appropriate nutritional intake as the patient's condition progresses. Dietary counseling is provided by qualified individuals, which may include a registered nurse, dietitian or nutritionist, when identified in the patient's plan of care.
- M. Direct Care Staff Member/Direct Care Volunteer. Individuals who provide care to patients within the parameters of their training and/or as determined by state law or statute.
- N. Health Assessment. An evaluation of the health status of a staff member or volunteer by a physician, other authorized healthcare provider, or registered nurse, pursuant to written standing orders and/or protocol approved by a physician's signature. The standing orders or protocol shall be reviewed annually by the physician, with a copy maintained at the Hospice.
- O. Hospice Aide. An individual supervised by a registered nurse who renders assistance with personal care to patients needing assistance with activities of daily living, and who meets minimum qualifications and training as set by the Hospice.
- P. Hospice. A centrally administered, interdisciplinary healthcare program, which provides a continuum of medically supervised palliative and supportive care for the terminally ill patient and the family or responsible party, including but not limited to home, Outpatient Services and Inpatient Services provided directly or through written agreement.
- Q. Hospice Facility. An institution, place, or building in which a licensed Hospice provides room, board, and Inpatient Services on a twenty-four (24) hour basis to individuals requiring Hospice care pursuant to the orders of a physician. Prior to construction or establishment of a new Hospice Facility, or increasing the number of beds in an existing facility, a Hospice Facility shall obtain a Certificate of Need from the Department.

- R. Inpatient Services. A continuum of medically supervised palliative and supportive care for the terminally ill patient and the family or responsible party provided by a Hospice for individuals intended to stay one (1) or more nights in an institution, place, or building licensed by the Department to provide room, board, and applicable care on a twenty-four (24) hour basis, such as a Hospice Facility, community residential care facility, nursing home, hospital, or general infirmary.
- S. Inspection. A visit by Department representative(s) for the purpose of determining compliance with this regulation.
- T. Interdisciplinary Team or Group. A group designated by the Hospice to provide or supervise care, treatment, and services provided by the Hospice. The group must include at least the following individuals: a physician, a registered nurse, a social worker, and a pastoral or other counselor.
- U. Investigation. A visit by Department representative(s) to an unlicensed or licensed Hospice or Hospice Facility for the purpose of determining the validity of allegations received by the Department.

V. Legend Drug.

- 1. Medication required by federal law to be labeled with any of the following statements prior to being dispensed or delivered:
 - a. "Caution: Federal law prohibits dispensing without prescription";
 - b. "Rx only" or;
- 2. Medication required by federal or state law to be dispensed pursuant to a prescription drug order or restricted to use by practitioners only; or
- 3. Any medication products designated by the South Carolina Board of Pharmacy to be a public health threat; or
 - 4. Any prescribed compounded prescription within the meaning of the Pharmacy Act.
- W. License. A certificate issued by the Department providing for the establishment and maintenance of a Hospice and, when specified on the face of the certificate, Hospice Facility in accordance with this regulation.
- X. Licensed Nurse. A person licensed by the South Carolina Board of Nursing as a registered nurse or licensed practical nurse or a person licensed as a registered nurse or licensed practical nurse who resides in another state that has been granted multi-state licensing privileges by the South Carolina Board of Nursing. This person may practice nursing in any facility or activity licensed by the Department subject to the provisions and conditions as indicated in the Nurse Licensure Compact Act.
- Y. Licensee. The individual, corporation, or public entity with whom rests the ultimate responsibility for maintaining statutory and regulatory standards for the licensed Hospice and, if applicable in accordance with the license issued, Hospice Facility.
- Z. Life-limiting Condition. A condition with no reasonable hope for a cure and will certainly prevent a child from surviving to adulthood.

- AA. Medication. A substance that has therapeutic effects, including, but not limited to, legend drugs, nonlegend and herbal products, vitamins, and nutritional supplements.
- BB. Minor. A person seventeen (17) years of age or younger who has not been emancipated in accordance with state law.
- CC. Multiple Location. A properly registered additional site, other than the licensed primary office, from which a parent hospice organization provides hospice services.
- <u>CCDD</u>. Nonlegend Medication. A medication which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws of this state and the federal government.
- <u>DDEE</u>. Occupational Therapist. A person currently licensed as such by the South Carolina Board of Occupational Therapy Examiners.
- EEFF. Outpatient Services. A continuum of medically supervised palliative and supportive care for the terminally ill patient and the family or responsible party provided by a Hospice and intended for individuals not staying one or more nights in an institution, place, or building licensed by the Department to provide room, board, and applicable care on a twenty-four (24) hour basis, such as a Hospice Facility, community residential care facility, nursing home, hospital, or general infirmary.
- FFGG. Palliative Care. Treatment that enhances comfort and improves the quality of an individual's life during the last phase of life.
- HH. Parent Hospice. A properly licensed Hospice that, in addition to its primary office, also provides hospice services from a multiple location.
- GGII. Patient. A person who receives care, treatment, or services from a Hospice licensed by the Department.
 - HHJJ. Pharmacist. An individual currently registered as such by the South Carolina Board of Pharmacy.
- <u>HKK</u>. Physical Assessment. An assessment of a patient by a physician or other authorized healthcare provider that addresses those issues identified in Section 1200 of this regulation.
- <u>JJLL</u>. Physical Therapist. An individual currently registered as such by the South Carolina Board of Physical Therapy Examiners.
- KKMM. Physician. An individual currently licensed by his or her state medical licensing board to practice medicine within that state.
- <u>LLNN</u>. Physician Assistant. An individual currently licensed as such by the South Carolina Board of Medical Examiners.
- MMOO. Plan of Care. A documented regimen of care, treatment, and services prepared by the Hospice for each patient based on assessment data and implemented for the benefit of the patient.
- PP. Primary Office. The main office of a Hospice program from which a parent hospice provides hospice services to patients and their families and from which a parent hospice performs oversight, administrative, and coordination of care duties for any multiple location.

- NNQQ. Quality Improvement Program. The process used by the Hospice to examine its methods and practices of providing care, identifying the opportunities to improve its performance, and taking actions that result in higher quality of care for the Hospice's patients.
- OORR. Repeat Violation. The recurrence of a violation cited under the same section of the regulation within a thirty-six (36) month period. The time period determinant of repeat violation status is not interrupted by licensee changes.
- <u>PPSS</u>. Respite Care. Short-term care provided to an individual to relieve the family members, responsible party, or other persons caring for the individual.
- QQTT. Responsible Party. A person who is authorized by law to make decisions on behalf of a patient, including, but not limited to, a court-appointed guardian or conservator, or person with a health care or other durable power of attorney.
- RRUU. Restraint. Any means by which movement of a patient is inhibited, including physical, mechanical, and/or chemical. In addition, devices shall be considered a restraint if a patient is unable to easily release from the device.
- <u>SSVV</u>. Revocation of License. An action by the Department to cancel or annul a license by recalling, withdrawing, or rescinding its authority to operate.
- TTWW. Social Worker. An individual who is licensed by the South Carolina Board of Social Worker Examiners.
- <u>UUXX</u>. Speech Therapist. An individual currently licensed as such by the South Carolina Board of Speech-Language Pathology and Audiology.
- <u>VVYY</u>. Staff Member. A person who is a compensated employee of the Hospice on either a full or part-time basis.
- <u>WWZZ</u>. Suspension of License. An action by the Department requiring a Hospice to cease operations for a period of time or to require a Hospice to cease admitting patients until such time as the Department rescinds that restriction.
- XXAAA. Terminally III. A medical prognosis that, if the disease runs its usual course, limits an individual's life expectancy to twenty-four (24) months or less; or, if the individual is twenty-one (21) years of age or less includes a Life-limiting Condition.
- <u>YYBBB</u>. Volunteer. An individual who performs tasks at the Hospice at the direction of the administrator or his or her designee without compensation.

Add Section 61-78.213 to read:

213. Multiple Locations

A. A Hospice shall not establish, operate, or maintain a multiple location or represent itself as such without first registering the multiple location with the Department and receiving approval of the registration from the Department confirming that the Hospice has properly filed the application to amend its license and include the multiple location.

- B. Hospices desiring to obtain approval for the registration of a multiple location shall file with the Department an application on a form prescribed, prepared, and furnished by the Department.
- C. A multiple location registration shall be effective until the expiration of the license of the parent hospice in effect at the time of the initial approval of the multiple location.

Revise Section 61-78.213 to read:

213214. Exceptions to Licensing Standards

The Department has the authority to make exceptions to these standards where it is determined that the health, safety, and well-being of the patients are not compromised, and provided the standard is not specifically required by statute.

Revise Section 61-78.401 to read:

401. General

When the Department determines that a Hospice-or, Hospice Facility, or multiple location is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such Hospice-or, Hospice Facility, or multiple location, the Department, upon proper notice to the licensee, may impose a monetary penalty, and deny, suspend, or revoke its license.

Revise Section 61-78.1608 to read:

1608. Disposition of Medications (I)

- A. Upon discharge or death of a patient, a Hospice in possession of unused medications belonging to the patient that do not constitute a controlled substance under 21 U.S.C. Section 802 shall release the unused medications to the patient, family member, or responsible party, as appropriate.
- B. Upon death of a patient <u>receiving services in a Hospice Facility</u>, a Hospice <u>Facility</u> in possession of unused medications belonging to the patient that constitutes a controlled substance under 21 U.S.C. Section 802 shall release the unused medication to an applicable person under 21 C.F.R. Section 1317.30 for disposal in accordance with requirements of the federal Drug Enforcement Administration. In the alternative, a facility that constitutes a long-term care facility under 21 C.F.R. 1300.01 may dispose of the unused medications in accordance with 21 C.F.R. Sections 1317.30 and 1317.80.
- C. Upon death of a patient receiving outpatient services, a Hospice shall comply with S.C. Code Section 44-71-85.
- €<u>D</u>. Upon discharge of a patient, a Hospice in possession of unused medications belonging to the patient that constitutes a controlled substance under 21 U.S.C. Section 802 shall release the unused medication to the "ultimate user" under 21 U.S.C. Section 802. In the alternative, a facility that constitutes a long-term care facility under 21 C.F.R. 1300.01 may dispose of the unused medications in accordance with 21 C.F.R. Sections 1317.30 and 1317.80 if authorized by the patient.
- $\underline{\text{DE}}$. Expired biologicals, medical supplies, and solutions shall be disposed of in accord with Hospice Facility policy.

Revise Section 61-78.2106 to read:

2106. Utility Rooms

- A. Soiled Utility Room: A Hospice Facility shall include at least one (1) soiled utility room per worknurses' station containing a clinical sink, work counter, waste receptacle and soiled linen receptacle.
- B. Clean Utility Room: A Hospice Facility shall include at least one (1) clean utility room per worknurses' station containing a counter with handwashing sink and space for the storage and assembly of supplies for nursing procedures.

Revise Section 61-78.2201 to read:

2201. Fire Protection

- A. A Hospice Facility shall include a partial, manual, automatic, and supervised fire alarm system. The system shall be arranged to transmit an alarm automatically to a third party by an approved method. The alarm system shall notify by audible and visual alarm all areas and floors of the building. The alarm system shall shut down central recirculating systems and outside air units that serve the area(s) of alarm origination as a minimum.
- B. All fire, smoke, heat, sprinkler flow, or manual fire alarming devices or systems must be connected to the main fire alarm system and trigger the system when they are activated.
 - C. A Hospice Facility shall include an NFPA 13 sprinkler system.
 - D. A Hospice Facility shall maintain a fire alarm pull station in or near each worknurses' station.

ATTACHMENT B STATE REGISTER NOTICE OF DRAFTING

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

CHAPTER 61

Statutory Authority: 1976 Code Sections 44-71-10 et seq.

Notice of Drafting:

The Department of Health and Environmental Control proposes to amend Regulation 61-78, *Standards for Licensing Hospices*. Interested persons may submit written comments to Gwen C. Thompson, Bureau Chief, Bureau of Health Facilities Licensing, South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina 29201 or via email at HealthRegComm@dhec.sc.gov. Comments may also be submitted electronically at the following address: http://www.scdhec.gov/Agency/RegulationsAndUpdates/PublicComments/, under the Notice of Drafting for R.61-78. To be considered, all comments must be received no later than 5:00 p.m., July 24, 2017, the close of the comment period.

Synopsis:

On May 19, 2017, Governor Henry McMaster signed into law Act No. 61 amending the Hospice Licensure Act. The Department proposes amending R.61-78 to incorporate the provisions of Act No. 61 into its oversight of hospices.

The Department may also include stylistic changes, which may include corrections for clarity and readability, grammar, punctuation, definitions, references, codification and overall improvement of the text of the regulation.

Legislative review will be required.

ATTACHMENT C

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

Document No. ____

R.61-78, Standards for Licensing Hospices

As of the July 24, 2017, close of the Notice of Drafting Comment period:

NAME	PUBLIC COMMENT	DEPARTMENT RESPONSE
1. Marisette Hasan, The Carolinas Center for Hospice and End of Life Care	The registration of all multiple locations and counties served by hospice providers. We recommend that each licensed facility be required to complete a "New" or "Updated" licensing application to update all prior information that will include a listing of all "multiple locations." We do not believe that the current application needs to be completely changed, but only slightly modified to remove the words "satellite locations" and replace with the words "multiple locations." This should simplify the process of revising the form to align with the definition of a "multiple location" in the statute. In addition, we are strongly opposed to the Dept. conducting "abbreviated surveys," prior to listing the "multiple locations" on the DHEC Website. We believe it is not the intent of the statute to add additional workload to the current survey process or incur additional expenses. We recommend that as soon as the Dept. receives the updated applications, the website should be updated within 3 business days, not after site visits are conducted. We believe that it is imperative for consumers and stakeholders to have immediate access to information regarding hospice provider locations in our state. Due to the large number of providers in the state, waiting until "multiple location" site visits are completed will unnecessarily delay the process of timely hospice service delivery.	Clarified. Section 213.B requires the Hospice to register the multiple location by filing an application on a form prescribed, prepared, and furnished by the Department. The regulation does not put forth all specific content of the application, as preparation, prescription, and furnishing of the application is an operational function. Additionally, the statute requires multiple locations to provide the full scope of hospice services in all geographical areas listed on the license. S.C. Code Section 44-71-70(B)(2). Therefore, the Department must inspect the multiple locations prior to listing them on the website to ensure the full scope of services is being provided.
2. Marisette Hasan, The Carolinas Center for Hospice and End of Life Care	Rotation of annual inspections to all registered multiple locations to ensure that the full scope of services are provided in every county served by the provider. Once providers complete an updated licensing application, we recommend that the rotation of licensing inspections to the multiple locations begin immediately with the provider's next scheduled survey. We recommend that the Dept. create an updated survey checklist that will include information to assist the inspection surveyors on how to determine that the full scope of services is being delivered in the county or counties served by the multiple location. In addition, we recommend that the Dept. utilize a group of providers to review the draft survey checklist prior to its implementation.	Acknowledged. The timing of inspections is an operational function that will comply with the governing statute. Additionally, survey checklists are part of the Department's processes and procedures and are not within the scope of this regulatory amendment.

NAME	PUBLIC COMMENT	DEPARTMENT RESPONSE
3. Marisette Hasan, The Carolinas Center for Hospice and End of Life Care	Annual mandatory data reporting by all licensed outpatient hospice providers. Since 1997, The Carolinas Center has been the steward of collecting, analyzing and distributing hospice outpatient data to not only providers, but to state and national stakeholders. Some of the benefits realized through mandatory reporting include, but are not limited to the following: • Preservation of hospice MCD benefits. For instance, our lobbyists and key legislators have said that our data and information was critical in forcing DHHS to rescind elimination of the hospice benefit in 2009 and to restoring the full benefit in 2010. Since Hospice is an optional service under the Medicaid program, the threat to the benefit remains a concern in the current economic environment of SC. The data collected by The Carolinas Center is the only outpatient hospice patient level information collected in the state. • Accurate accounting for the depth of hospice service delivery by providers throughout the state. In NC, hospice data reporting and collection is mandatory. However, in SC, this was an optional report; with the new statute, having all providers participate allows for the most exact accurate accounting of hospice activity across SC. Knowing the number of total hospice provider deaths per county is one statistic that is key to encouraging physicians to refer hospice patients in a timely manner. • National Data collection activities. After analysis is completed by The Carolinas Center, the data is sent to NHPCO for inclusion in the National Data Set. The National Data Set represents the most accurate picture of hospice activity across the country. • State Data Collection. The collection of state level hospice data will help provide a snapshot of quality hospice care delivery that are necessary elements to demonstrate the value that hospice programs offer for innovative end of life care delivery models. Data collection of this magnitude will allow SC to emerge as a leader for publicly available information regarding hospice progr	Clarified. Section 706 requires Hospices to complete and return a "Joint Annual Report" (JAR) to the Revenue and Fiscal Affairs Office (RFA) within the time period specified by the Department. Therefore, the reported data will be collected and managed by the RFA. Additionally, failure to comply with JAR reporting requirements is currently a Class III violation.

NAME	PUBLIC COMMENT	DEPARTMENT RESPONSE
4. Marisette Hasan, The Carolinas Center for Hospice and End of Life Care	It is imperative that the Dept. validates the value of obtaining an in depth view of hospice service delivery in SC through the JAR for outpatient hospice data. There are more than 100 licensed outpatient hospice providers versus 14 inpatient hospice providers. As you are aware, there is greater opportunity for variability in hospice service delivery due to the number of providers and the counties served. The outpatient hospice JAR should have data elements that are a reflection of the types of services JAR should have data elements that are a reflection of the types of services provided in our state to ensure that there are no gaps in hospice service delivery in any of our 46 counties. As stated previously, many hospice providers have reported in depth hospice data to the Carolinas Center since 1997, and their input in the creation of an outpatient data reporting tool, in addition to the assistance of The Carolinas Center, would be invaluable to the implementation of this report by the Dept. If it is determined that the Dept. is not willing to convene a hospice provider stakeholder group with a representative from the Carolinas Center to assist in the creation of an outpatient data reporting tool, The Carolinas Center recommends that at a minimum, the following data elements be included in the tool: • Hospice Patients Admitted by Diagnosis • Hospice Patients Admitted by Age • Hospice Patients Admitted by Rage • Hospice Patients Admitted by Race • Hospice Patient Deaths by County and by Location (see examples above) • Hospice Patient Live Discharges by Diagnosis • Hospice Patient Live Discharges by Diagnosis • Hospice Patient Admission Patient Days by Diagnosis • Hospice Porgram Staffing and Visits by Discipline • Percentage of Hospice Days by Payer Source • Percentage of Hospice Patients Serviced by Provider by County • Hospice Porgram Staffing and V	Acknowledged.

NAME	PUBLIC COMMENT	DEPARTMENT RESPONSE
5. Marisette Hasan, The Carolinas Center for Hospice and End of Life Care	Lastly, we recommend, that if a draft outpatient reporting tool for the JAR is developed without convening a group of hospice stakeholders to assist in the development of the new tool, that the hospice provider community be allowed to comment on the new outpatient data reporting tool prior to its implementation by the Dept.	Acknowledged. The Department will continue its practice of stakeholder outreach in implementing the regulatory amendments.
6. Cindy Morgan, South Carolina Home Care & Hospice Association	Regarding Multiple listings: We appreciate the effort to list these multiple hospice locations online which will give a complete listing of all hospices operating in the state. These Medicare certified licensed hospices are expansions of the parent office; therefore the parent office has met the expectations set forth by Medicare. We believe that on-site inspections of these additional locations before they may be listed in the directory would certainly be labor intensive, expensive and unnecessary.	Not adopted. The statute requires multiple locations to provide the full scope of hospice services in all geographical areas listed on the license. S.C. Code Section 44-71-70(B)(2). Therefore, the Department must inspect the multiple locations prior to listing them on the website to ensure the full scope of services is being provided.
7. Cindy Morgan, South Carolina Home Care & Hospice Association	Regarding Data Supplement Elements: Again, we are grateful to you for your efforts to start collecting data related to hospice services in our state. We would offer the following suggestions related to data elements that would help paint the picture of the delivery of hospice services in our state and in our counties. This will enable all to see more clearly the accessibility or lack of accessibility across the state. • Demographics of Hospice (Outpatient) • Patient Demographics • Volume of Patients—Census, Average Census, Length of Stay, Deaths, Level of Care, Payer Source • Patient Origin by County • Unduplicated Admissions • Deaths by Location • Primary Diagnosis of Hospice Patient • Staffing (FTEs); Caseloads per discipline • Volunteer Program • Bereavement Program • Inpatient Facilities • Census for GIP and/or Residential • Average Census • Length of Stay The State of North Carolina has a similar data collection process. We are happy to work with you as you develop the data collection tool.	Acknowledged.
8. Cindy Morgan, South Carolina Home Care & Hospice Association	Regarding On-Site Visits: We support on-site inspections to include visits to the multiple locations and not just the parent hospice. This will ensure that full services required by the licensure are being delivered in all areas the hospice is licensed to provide services.	Acknowledged.

NAME	PUBLIC COMMENT	DEPARTMENT RESPONSE
9. Cindy		
Morgan,	Regarding Drug Disposal: We applaud South Carolina for taking	
South	this step to help decrease accessibility to the controlled substances	
Carolina	left upon the death of a patient. We stand ready and willing to work	Acknowledged.
Home Care	with the department to deliver education to providers in order for	
& Hospice	them to comply with this regulation.	
Association		,

BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

Summary Sheet November 9, 2017

X Action

I. SUBJECT: Placement of orthofluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl into Schedule I of the Controlled Substances Act

II. FACTS: Controlled substances are governed by the S.C. Controlled Substances Act (CSA), found at Title 44, Chapter 53, of the S.C. Code of Laws. Schedule I substances are listed in S.C. Code Ann. Section 44-53-190. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances shall be made," controlled substances are generally designated by the General Assembly upon recommendation by DHEC. Section 44-53-160(C) provides a process by which DHEC can expeditiously designate a substance as a controlled substance if the federal government has so designated. Section 44-53-160(C) states:

If a substance is added, deleted, or rescheduled as a controlled substance pursuant to federal law or regulation, the department shall, at the first regular or special meeting of the South Carolina Board of Health and Environmental Control within thirty days after publication in the federal register of the final order designating the substance as a controlled substance or rescheduling or deleting the substance, add, delete, or reschedule the substance in the appropriate schedule. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection has the full force of law unless overturned by the General Assembly. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection must be in substance identical with the order published in the federal register effecting the change in federal status of the substance. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairmen of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee, and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

On October 26, 2017, the Administrator of the Drug Enforcement Administration issued a temporary scheduling order to schedule the synthetic opioids, N-(2- fluorophenyl)-N-(1-phenethylpiperidin- 4-yl)propionamide (ortho-fluorofentanyl or 2-fluorofentanyl), N-(1- phenethylpiperidin-4-yl)-Nphenyltetrahydrofuran-2-carboxamide (tetrahydrofuranyl fentanyl), and 2- methoxy-N-(1- phenethylpiperidin-4-yl)- N-phenylacetamide (methoxyacetyl fentanyl), into Schedule I. This action was based on a finding by the Administrator that the placement of orthofluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl into Schedule I of the Controlled Substances Act was necessary to avoid an imminent hazard to the public safety. Thus, the regulatory controls and administrative, civil, and criminal sanctions applicable to Schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle, orthofluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl. The federal temporary scheduling order

became effective October 26, 2017. https://www.gpo.gov/fdsys/pkg/FR-2017-10-26/pdf/2017-23206.pdf

III. ANALYSIS:

The population likely to abuse orthofluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl overlaps with the population abusing prescription opioid analgesics, heroin, fentanyl, and other fentanyl-related substances. This is evidenced by the routes of drug administration and drug use history documented in orthofluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl fatal overdose cases and encounters of the substance by law enforcement officials. Because abusers of these substances are likely to obtain them through unregulated sources, the identity, purity, and quantity are uncertain and inconsistent, thus posing significant adverse health risks to the end user. Individuals who initiate (i.e. use a drug for the first time) the substance abuse are likely to be at risk of developing substance use disorder, overdose, and death similar to that of other opioid analgesics (e.g., fentanyl, morphine, etc.).

The recreational abuse of fentanyl-like substances continues to be a significant concern. These substances are distributed to users, often with unpredictable outcomes. orthoFluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl have recently been encountered by law enforcement and public health officials. Adverse health effects and outcomes are demonstrated by fatal overdose cases involving these substances. The documented adverse health effects of orthofluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl are consistent with those of other opioids.

Use of ortho-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl have been associated with numerous fatalities. At least 13 confirmed overdose deaths involving ortho-fluorofentanyl abuse have been reported from Georgia (1), North Carolina (11), and Texas (1). At least two confirmed overdose deaths involving tetrahydrofuranyl fentanyl have been reported from New Jersey (1) and Wisconsin (1). At least two confirmed overdose deaths involving methoxyacetyl fentanyl have been reported from Pennsylvania. As the data demonstrate, the potential for fatal and non-fatal overdoses exists for orthofluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl and these substances pose an imminent hazard to the public safety.

When determining whether a substance should be placed into Schedule I of the S.C. Controlled Substances Act, Section 44-53-180 of the S.C. Code of Laws requires the Department place a substance in Schedule II if it meets the following criteria:

- (a) A high potential for abuse;
- (b) No accepted medical use in treatment in the United States; and
- (c) A lack of accepted safety for use in treatment under medical supervision.

S.C. Code Ann. § 44-53-180.

DEA conducted its own review and determined that ortho-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl met the criteria for placement in schedule I of the federal CSA because a review of available data showed it had a high potential for abuse, no currently accepted

medical use in treatment in the United States, and a lack of accepted safety for use in treatment under medical supervision.

IV. RECOMMENDATION:

As DEA has determined the placement of ortho-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl into schedule I of the federal CSA is necessary, the Department recommends the permanent placement of ortho-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl into Schedule I for Controlled Substances in South Carolina and amend S.C. Code Section 44-53-190(B) to include:

N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl) propionamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other names: ortho-fluorofentanyl, 2-fluorofentanyl) N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: tetrahydrofuranyl fentanyl) 2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: methoxyacetyl fentanyl).

Submitted by:

Lisa Thomson

Chief, Bureau of Drug Control

Shelly Kelly

Deputy Director for Health Regulations

Attachment:



years, must justify such requests, for example by proposing development, environmental, and recreation enhancements in a license amendment application accompanied by a request that the Commission extend their license term.²¹

III. Document Availability

21. In addition to publishing the full text of this document in the Federal Register, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (http://www.ferc.gov) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

22. From FERC's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field. User assistance is available for eLibrary and the Commission's Web site during normal business hours from FERC Online Support at 202-502-6652 (toll free at 1-866-208-3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502-8371, TTY (202)502-8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

By the Commission. Issued: October 19, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017-23286 Filed 10-25-17; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-473]

Schedules of Controlled Substances: Temporary Placement of ortho-Fluorofentanyl, Tetrahydrofuranyl Fentanyl, and Methoxyacetyl Fentanyl Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice. **ACTION:** Temporary amendment; temporary scheduling order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this temporary scheduling order to schedule the synthetic opioids, N-(2fluorophenyl)-N-{1-phenethylpiperidin-4-yl)propionamide (ortho-fluorofentanyl or 2-fluorofentanyl), N-(1phenethylpiperidin-4-yl)-Nphenyltetrahydrofuran-2-carboxamide (tetrahydrofuranyl fentanyl), and 2methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (methoxyacetyl fentanyl), into Schedule I. This action is based on a finding by the Administrator that the placement of orthofluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl into Schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to Schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle, orthofluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl. DATES: This temporary scheduling order is effective October 26, 2017, until October 28, 2019. If this order is extended or made permanent, the DEA will publish a document in the Federal Register.

FOR FURTHER INFORMATION CONTACT:

Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

Section 201 of the Controlled Substances Act (CSA), 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into Schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling ¹ for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA, 21U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into Schedule I of the CSA.2 The Administrator transmitted notice of his intent to place ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl in Schedule I on a temporary basis to the Assistant Secretary for Health of HHS by letter. Notice for these actions was transmitted on the following dates: May 19, 2017 (ortho-fluorofentanyl) and July 5, 2017 (tetrahydrofuranyl fentanyl and methoxyacetyl fentanyl). The Assistant Secretary responded by letters dated June 9, 2017 (ortho-fluorofentanyl) and July 14, 2017 (tetrahydrofuranyl fentanyl and methoxyacetyl fentanyl), and advised that based on review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications or approved new drug applications for ortho-

²¹ See, e.g., Idaho Power Co., 132 FERC ¶ 62,001 (2010) (10-year extension of the license term due to the costs of replacing the project's existing powerhouse and increasing generating capacity); PPL Hollwood, LLC, 129 FERC ¶ 62,092 (2009) (16-year extension of license term due to costs associated with the constructing a new powerhouse, installing two turbine generating units at the existing powerhouse, and various environmental measures).

¹ Though DEA has used the term "final order" with respect to temporary scheduling orders in the past, this document adheres to the statutory language of 21 U.S.C. 811(h), which refers to a "temporary scheduling order." No substantive change is intended.

² As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

fluorofentanyl, tetrahydrofuranyl fentanyl, or methoxyacetyl fentanyl. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, or methoxyacetyl fentanyl into Schedule I of the CSA. The DEA has taken into consideration the Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). ortho-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl are not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for orthofluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the control of ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl in Schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, and as required by 21 U.S.C. 811(h)(1)(A), a notice of intent to issue a temporary order to schedule orthofluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl was published in the Federal Register on September 12, 2017. 82 FR 42754.

To find that placing a substance temporarily into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA, 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed into Schedule I. 21 U.S.C. 811(h)(1). Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

Available data and information for ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl, summarized below, indicate that these synthetic opioids have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The DEA's three-factor analysis, and the Assistant

Secretary's June 9, 2017 and July 14, 2017 letters are available in their entirety under the tab "Supporting Documents" of the public docket of this action at www.regulations.gov under FDMS Docket ID: DEA-2017-0005 (Docket Number DEA-473).

Factor 4. History and Current Pattern of Abuse

The recreational abuse of fentanyl-like substances continues to be a significant concern. These substances are distributed to users, often with unpredictable outcomes. ortho-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl have recently been encountered by law enforcement and public health officials. Adverse health effects and outcomes are demonstrated by fatal overdose cases involving these substances. The documented adverse health effects of ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl are consistent with those of other opioids.

On October 1, 2014, the DEA implemented STARLiMS (a web-based. commercial laboratory information management system) to replace the System to Retrieve Information from Drug Evidence (STRIDE) as its laboratory drug evidence data system of record. DEA laboratory data submitted after September 30, 2014, are reposited in STARLiMS. Data from STRIDE and STARLiMS were queried on June 19, 2017. STARLIMS registered four reports containing ortho-fluorofentanyl from California and five reports containing tetrahydrofuranyl fentanyl from Florida and Missouri. According to STARLiMS, the first laboratory submissions of orthofluorofentanyl and tetrahydrofuranyl fentanyl occurred in April 2016, and March 2017, respectively.

The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by other federal, state, and local forensic laboratories across the country. Data from NFLIS was queried on June 20, 2017. NFLIS registered three reports containing ortho-fluorofentanyl from state or local forensic laboratories in Virginia.3 According to NFLIS, the first report of ortho-fluorofentanyl was reported in September 2016. NFLIS registered two reports containing tetrahydrofuranyl fentanyl from state or local forensic laboratories in New Jersey and was first reported in January 2017. The identification of methoxyacetyl fentanyl in drug evidence submitted in April 2017 was reported to DEA from a local laboratory in Ohio.⁴ The DEA is not aware of any laboratory identifications of *ortho*-fluorofentanyl prior to 2016 or identifications of tetrahydrofuranyl fentanyl or methoxyacetyl fentanyl prior to 2017.

Evidence suggests that the pattern of abuse of fentanyl analogues, including ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl, parallels that of heroin and prescription opioid analgesics. Seizures of ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl have been encountered in powder form similar to fentanyl and heroin and have been connected to fatal overdoses.

Factor 5. Scope, Duration and Significance of Abuse

Reports collected by the DEA demonstrate ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl are being abused for their opioid properties. Abuse of ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl have resulted in mortality (see DEA 3-Factor Analysis for full discussion). The DEA collected post-mortem toxicology and medical examiner reports on 13 confirmed fatalities associated with orthofluorofentanyl which occurred in Georgia (1), North Carolina (11), and Texas (1), two confirmed fatalities associated with tetrahydrofuranyl fentanyl which occurred in New Jersey (1) and Wisconsin (1), and two confirmed fatalities associated with methoxyacetyl fentanyl which occurred in Pennsylvania. It is likely that the prevalence of these substances in opioid related emergency room admissions and deaths is underreported as standard immunoassays may not differentiate fentanyl analogues from fentanyl.

ortho-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl have been identified in drug evidence collected by law enforcement. NFLIS and STARLiMS have a total of seven drug reports in which ortho-fluorofentanyl was identified in drug exhibits submitted to forensic laboratories in 2016 from law enforcement encounters in California and Virginia and seven drug reports in which tetrahydrofuranyl fentanyl was identified in drug exhibits submitted to forensic laboratories in 2017 from law

³ Data are still being collected for March 2017– June 2017 due to the normal lag period for labs reporting to NFLIS.

⁴ Email from Cuyahoga County Medical Examiner's Office, to DEA (May 8, 2017 02:29 p.m. EST) (on file with DEA).

enforcement encounters in Florida, Missouri, and New Jersey. The identification of methoxyacetyl fentanyl in drug evidence submitted in April 2017 was reported to DEA from Ohio.

The population likely to abuse orthofluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl overlaps with the population abusing prescription opioid analgesics, heroin, fentanyl, and other fentanyl-related substances. This is evidenced by the routes of drug administration and drug use history documented in orthofluorofentanyl and tetrahydrofuranyl fentanyl fatal overdose cases. Because abusers of ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl are likely to obtain these substances through unregulated sources, the identity, purity, and quantity are uncertain and inconsistent, thus posing significant adverse health risks to the end user. Individuals who initiate (i.e. use a drug for the first time) ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, or methoxyacetyl fentanyl abuse are likely to be at risk of developing substance use disorder, overdose, and death similar to that of other opioid analgesics (e.g., fentanyl, morphine, etc.).

Factor 6. What, if Any, Risk There Is to the Public Health

ortho-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl exhibit pharmacological profiles similar to that of fentanyl and other μ-opioid receptor agonists. The toxic effects of orthofluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl in humans are demonstrated by overdose fatalities involving these substances. Abusers of ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl may not know the origin, identity, or purity of these substances, thus posing significant adverse health risks when compared to abuse of pharmaceutical preparations of opioid analgesics, such as morphine and

Based on information received by the DEA, the misuse and abuse of ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl lead to the same qualitative public health risks as heroin, fentanyl and other opioid analgesic substances. As with any non-medically approved opioid, the health and safety risks for users are high. The public health risks attendant to the abuse of heroin and opioid analgesics are well established and have resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses.

ortho-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl have been associated with numerous fatalities. At least 13 confirmed overdose deaths involving ortho-fluorofentanyl abuse have been reported from Georgia (1), North Carolina (11), and Texas (1). At least two confirmed overdose deaths involving tetrahydrofuranyl fentanyl have been reported from New Jersey (1) and Wisconsin (1). At least two confirmed overdose deaths involving methoxyacetyl fentanyl have been repored from Pennsylvania. As the data demonstrate, the potential for fatal and non-fatal overdoses exists for orthofluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl and these substances pose an imminent hazard to the public safety.

Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information, summarized above, the continued uncontrolled manufacture. distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of orthofluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl poses an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, or methoxyacetyl fentanyl in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in Schedule I. Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl indicate that these substances have a high potential for abuse, no currently accepted medical use in treatment in the United States. and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Administrator, through letters dated May 19, 2017 (ortho-fluorofentanyl) and July 5, 2017 (tetrahydrofuranyl fentanyl and methoxyacetyl fentanyl), notified the Assistant Secretary of the DEA's intention to temporarily place these substances in Schedule I. A notice of intent was subsequently published in

the **Federal Register** on September 12, 2017. 82 FR 42754.

Conclusion

In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, herein sets forth the grounds for his determination that it is necessary to temporarily schedule *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl into Schedule I of the CSA, and finds that placement of these synthetic opioids into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety.

Because the Administrator hereby finds it necessary to temporarily place these synthetic opioids into Schedule I to avoid an imminent hazard to the public safety, this temporary order scheduling *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl is effective on the date of publication in the **Federal Register**, and is in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2).

The CSA sets forth specific criteria for scheduling a drug or other substance. Permanent scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The permanent scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the permanent scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C.

Requirements for Handling

Upon the effective date of this temporary order, ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl will become subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of Schedule I controlled substances including the following:

- 1. Registration. Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312, as of October 26, 2017. Any person who currently handles ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl, and is not registered with the DEA, must submit an application for registration and may not continue to handle ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl as of October 26, 2017, unless the DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of Schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of these substances in a manner not authorized by the CSA on or after October 26, 2017 is unlawful and those in possession of any quantity of these substances may be subject to prosecution pursuant to the
- 2. Disposal of stocks. Any person who does not desire or is not able to obtain a Schedule I registration to handle ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl, must surrender all quantities of currently held ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl, and methoxyacetyl fentanyl.

3. Security. ortho-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl are subject to Schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.93, as of October 26, 2017.

- 4. Labeling and packaging. All labels, labeling, and packaging for commercial containers of ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302. Current DEA registrants shall have 30 calendar days from October 26, 2017, to comply with all labeling and packaging requirements.
- 5. *Inventory*. Every DEA registrant who possesses any quantity of *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl on the effective date of this order must take

- an inventory of all stocks of these substances on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including orthofluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.
- 6. Records. All DEA registrants must maintain records with respect to ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, and 1312, 1317 and § 1307.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.
- 7. Reports. All DEA registrants who manufacture or distribute orthofluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312 as of October 26, 2017.
- 8. Order Forms. All DEA registrants who distribute ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of October 26, 2017.
- 9. Importation and Exportation. All importation and exportation of ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of October 26, 2017.
- 10. Quota. Only DEA registered manufacturers may manufacture orthofluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of October 26, 2017.
- 11. Liability. Any activity involving ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl not authorized by, or in violation of the CSA, occurring as of October 26, 2017, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in Schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of the Administrative Procedure Act (APA) at 5 U.S.C. 553, do not apply to this temporary scheduling action. In the alternative, even assuming that this action might be subject to 5 U.S.C. 553, the Administrator finds that there is good cause to forgo the notice and comment requirements of 5 U.S.C. 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Further, the DEA believes that this temporary scheduling action is not a "rule" as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget.

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient

federalism implications to warrant the preparation of a Federalism Assessment.

As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. However, if this were a rule, pursuant to the Congressional Review Act, "any rule for which an agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the federal agency promulgating the rule determines." 5 U.S.C. 808(2). It is in the public interest to schedule these substances immediately to avoid an imminent hazard to the public safety. This temporary scheduling action is taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h) exempts

the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie 21 U.S.C. 811(h), that is, the DEA's need to move quickly to place these substances into Schedule I because it poses an imminent hazard to the public safety, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, this order shall take effect immediately upon its publication. The DEA has submitted a copy of this temporary order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small **Business Regulatory Enforcement** Fairness Act of 1996 (Congressional Review Act), 5 U.S.C. 801-808 because, as noted above, this action is an order, not a rule.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add reserved paragraphs (h)(15) through (18) and paragraphs (h)(19), (20), and (21) to read as follows:

§1308.11 Schedule I.

Dated: October 17, 2017. Robert W. Patterson,

Acting Administrator.

[FR Doc. 2017-23206 Filed 10-25-17; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9815]

RIN 1545-BM33

Dividend Equivalents From Sources Within the United States; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and temporary regulations; Correcting amendments.

SUMMARY: This document contains corrections to final and temporary regulations (TD TD 9815), which were published in the **Federal Register** on Tuesday, January 24, 2017.

DATES: *Effective Date:* These corrections are effective October 26, 2017.

Applicability Date: The corrections to $\S\S 1.1.871-15$, 1.871-15T, 1.1441-1(e)(5)(v)(B)(4), (e)(6), and (f)(5), 1.1441-2, 1.1441-7, and 1.1461-1 are applicable on January 19, 2017.

FOR FURTHER INFORMATION CONTACT: D. Peter Merkel or Karen Walny at 202–317–6938 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations that are the subject of these corrections are §§ 1.871–15, 1.871–15T, 1.1441–1, 1.1441–2, 1.1441–7, and 1.1461–1, promulgated under sections 871(m) and 7805 of the Internal Revenue Code. These regulations affect foreign persons that hold certain financial products providing for payments that are contingent upon or determined by reference to U.S. source dividends, as well withholding agents with respect to dividend equivalents and certain other parties to section 871(m) transactions and their agents.

Need for Correction

As published, TD 9815 contains errors that may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

■ Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

§1.871-15 [Amended]

- Par. 2. Section 1.871–15 is amended by:
- 1. Removing paragraph (r)(2).
- 2. Redesignating paragraphs (r)(3), (4), and (5), as (r)(2), (3), and (4), respectively.

§1.871-15 [Amended]

■ Par. 3. For each section listed in the table, remove the language in the "Remove" column and add in its place the language in the "Add" column as set forth below:

Section	Remove	Add
		ELI. More described in this paragraph (I)(1) qualified intermediary withholding agreement

BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

Summary Sheet November 9, 2017

X	_ Action
	Information

I. SUBJECT: Placement of the synthetic cannabinoid, methyl 2-(1-(4-fluorobenzyl)-1 *H*-indazole-3-carboxamido)-3-methylbutanoate [FUB-AMB, MMB-FUBINACA, AMB-FUBINACA], and its optical, positional, and geometric isomers, salts, and salts of isomers into schedule I.

II. FACTS: Controlled substances are governed by the Controlled Substances Act (CSA), found at Title 44, Chapter 53, of the S.C. Code of Laws. Section 44-53-160 is titled "Manner in which changes in schedule of controlled substances shall be made." Pursuant to Section 44-53-160, controlled substances are generally designated by the General Assembly, upon recommendation by DHEC. Schedule I substances are listed in § 44-53-190. Section 44-53-160(C) provides a process by which DHEC can expeditiously designate a substance as a controlled substance if the federal government has so designated.

§ 44-53-160(C) states:

If a substance is added, deleted, or rescheduled as a controlled substance pursuant to federal law or regulation, the department shall, at the first regular or special meeting of the South Carolina Board of Health and Environmental Control within thirty days after publication in the federal register of the final order designating the substance as a controlled substance or rescheduling or deleting the substance, add, delete, or reschedule the substance in the appropriate schedule. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection has the full force of law unless overturned by the General Assembly. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection must be in substance identical with the order published in the federal register effecting the change in federal status of the substance. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairman of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

The U.S. Department of Justice, Drug Enforcement Administration (DEA), published on November 3, 2017, its notice of intent to temporarily schedule the the synthetic cannabinoid, methyl 2-(1-(4-fluorobenzyl)-1 *H*-indazole-3-carboxamido)-3-methylbutanoate [FUB-AMB, MMB-FUBINACA, AMB-FUBINACA], and its optical, positional, and geometric isomers, salts, and salts of isomers into schedule I. This action was based on a finding by the Administrator that the placement of this synthetic cannabinoid into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. https://www.gpo.gov/fdsys/pkg/FR-2017-11-03/pdf/2017-24010.pdf

III. SUMMARY:

Background

The South Carolina Board of Health ane Environmental Control has scheduled a similar compound on February 27, 2014. In order to assure there is no question as to the placement of synthetic cannabinoid, methyl 2-(1-(4-fluorobenzyl)-1 *H*-indazole-3-carboxamido)-3-methylbutanoate [FUB-AMB, MMB-FUBINACA, AMB-FUBINACA], and its optical, positional, and geometric isomers, salts, and salts of isomers into schedule I, the Bureau of Drug Control provides this information as background to the current DEA action.

To find that placing a substance temporarily into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the DEA Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA, 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. $21 \text{ U.S.C.} \\ 812(b)(1)$.

Available data and information for FUB-AMB, summarized below, indicate that this synthetic cannabinoid (SC) has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

The illicit use of the synthetic cannabinoid (SC) methyl 2-(1-(4-fluorobenzyl)-1 *H*-indazole-3-carboxamido)-3-methylbutanoate (Street names: FUB-AMB, MMB-FUBINACA, AMB-FUBINACA) has dramatically increased over the past 12 months posing an imminent threat to public safety. FUB-AMB has no accepted medical use in

the United States. Use of this specific SC has been reported to result in adverse effects in humans. Use of other SCs has resulted in signs of addiction and withdrawal and based on the similar pharmacological profile of FUB-AMB, it is believed that there will be similar observed adverse effects.

FUB-AMB is a SC that has pharmacological effects similar to the Schedule I hallucinogen THC and other temporarily and permanently controlled Schedule I synthetic cannabinoid substances. In addition, the misuse of FUB-AMB has been associated with multiple overdoses requiring emergency medical intervention. With no approved medical use and limited safety or toxicological information, FUB-AMB has emerged on the designer drug market, and the abuse of this substance for its psychoactive properties is concerning.

The designer drug products laced with SCs, including FUB-AMB, are often sold under the guise of "herbal incense" or "potpourri," use various product names, and are routinely labeled "not for human consumption." Additionally, these products are marketed as a "legal high" or "legal alternative to marijuana" and are readily available over the Internet, in head shops, or sold in convenience stores. There is an incorrect assumption that these products are safe, that they are a synthetic form of marijuana, and that labeling these products as "not for human consumption" is a legal defense to criminal prosecution.

It is believed most abusers of SCs or SC-related products are smoking the product following application to plant material. Law enforcement has also begun to encounter new variations of SCs in liquid form. It is believed abusers have been applying the liquid to hookahs or "e-cigarettes," which allows the user to administer a vaporized liquid that can be inhaled.

SCs including FUB-AMB continue to be encountered on the illicit market regardless of scheduling actions that attempt to safeguard the public from the adverse effects and safety issues associated with these substances. Novel substances are encountered each month, differing only by small modifications intended to avoid prosecution while maintaining the pharmacological effects. Law enforcement and health care professionals continue to report the abuse of these substances and their associated products.

As described by the National Institute on Drug Abuse (NIDA), many substances being encountered in the illicit market, specifically SCs, have been available for years but have reentered the marketplace due to a renewed popularity. The threat of serious injury to the individual following the ingestion of FUB-AMB and other SCs persists.

FUB-AMB was first encountered in June 2014, in locations including: Arizona, Arkansas, California, Colorado, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, **South Carolina**, Tennessee, Texas, Utah, Virginia,

Wisconsin and Wyoming. FUB-AMB has been identified in overdose cases attributed to its abuse. Adverse health effects reported from these incidents involving FUB-AMB have included: Nausea, persistent vomiting, agitation, altered mental status, seizures, convulsions, loss of consciousness, and cardiotoxicity. By sharing pharmacological similarities with Schedule I substances (Δ9-THC, JWH-018 and other temporarily and permanently controlled schedule I SCs), SCs pose a risk to the abuser. While these adverse effects have been shown by a variety of SCs, similar concerns remain regarding the welfare of the user as it relates to abuse of products laced with FUB-AMB. The risk of adverse health effects is further increased by the fact that similar products vary in the composition and concentration of SCs applied on the plant material.

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information summarized above, the continued uncontrolled manufacture, distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of FUB-AMB poses an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for FUB-AMB in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for FUB-AMB indicate that this SC has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Administrator, through a letter dated May 19, 2017, notified the Assistant Secretary of the DEA's intention to temporarily place FUB-AMB in Schedule I. A notice of intent was subsequently published in the Federal Register on September 11, 2017. 82 FR 42624.

Conclusion

In accordance with the provisions of section 201(h) of the CSA, <u>21 U.S.C. 811(h)</u>, the Administrator considered available data and information, and herein set forth the grounds for his determination that it is necessary to temporarily schedule methyl 2-(1-(4-fluorobenzyl)-1 *H*-indazole-3-carboxamido)-3-methylbutanoate [FUB-AMB, MMB-FUBINACA] into schedule I of the CSA to avoid an imminent hazard to the public safety.

Upon the effective date of this final order, FUB-AMB will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of this substance in a manner not authorized by the CSA on or after November 3, 2017 is unlawful and those

in possession of any quantity of this substance may be subject to prosecution pursuant to the CSA.

Any activity involving FUB-AMB not authorized by, or in violation of the CSA, occurring as of November 3, 2017, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

IV. RECOMMENDATION: For the reasons set forth above, the Bureau of Drug Control recommends the Board designate methyl 2-(1-(4-fluorobenzyl)-1 *H*-indazole-3-carboxamido)-3-methylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: FUB-AMB, MMB-FUBINACA, AMB-FUBINACA) and place into Schedule I of the SC Controlled Substances Act.

Submitted by:

Lisa Thomson

Chief, Bureau of Drug Control

Shelly Kelly

Deputy Director for Health Regulations

Attachments: Federal Register / Vol. 82, No. 212 / Friday, November 3, 2017 Board Designation, February 27, 2014



(2) The merits of the proceeding if all parties known to be interested in the proceeding have been given notice and an opportunity to participate. A memorandum of any such discussion shall be included in the record of the

proceeding.

(c) No interested person outside the Department shall make or knowingly cause to be made to an employee of the Department who is or may reasonably be expected to be involved in the decisional process of the proceeding, an ex parte communication relevant to the merits of the proceeding except as provided in paragraph (a) of this section.

- (d) If an employee of the Department who is or may reasonably be expected to be involved in the decisional process of the proceeding receives or makes or knowingly causes to be made a communication prohibited by this section, the Department shall place on the public record of the proceeding:
- (1) All such written communications;(2) Memoranda stating the substance
- of all such oral communications; and (3) All written responses, and memoranda, stating the substance of all oral responses thereto.
- (e) Upon receipt of a communication knowingly made or knowingly caused to be made by a party in violation of this section, the Department may, to the extent consistent with the interest of justice and the policy of the underlying statute, require the party to show cause why his claim or interest in the proceeding should not be dismissed, denied, disregarded, or otherwise adversely affected on account of such
- (f) This section does not constitute authority to withhold information from Congress.

§ 1.818 Additional documents to be filed with hearing clerk.

In addition to the documents or papers required or authorized by the foregoing provisions of this subpart to be filed with the hearing clerk, the hearing clerk shall receive for filing and shall have custody of all papers, reports, records, orders, and other documents which relate to the administration of any order and which the Secretary is required to issue or to approve.

§ 1.819 Hearing before Secretary.

(a) The Secretary may act in the place and stead of a Judge in any proceeding herein. When the Secretary so acts, the hearing clerk shall transmit the record to the Secretary at the expiration of the period provided for the filing of proposed findings of fact, conclusions, and orders, and the Secretary shall then, after due consideration of the record, issue the final decision in the proceeding.

(b) The Secretary may issue a tentative decision in which event the parties shall be afforded an opportunity to file exceptions before the issuance of the final decision.

Stephen Alexander Vaden,

Principal Deputy General Counsel, Office of the General Counsel.

[FR Doc. 2017–23877 Filed 11–2–17; 8:45 am] **BILLING CODE 3410–90–P**

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-472]

Schedules of Controlled Substances: Temporary Placement of FUB-AMB Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice. ACTION: Temporary amendment; temporary scheduling order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this temporary scheduling order to schedule the synthetic cannabinoid, methyl 2-(1-(4-fluorobenzyl)-1Hindazole-3-carboxamido)-3methylbutanoate [FUB-AMB, MMB-FUBINACA, AMB-FUBINACA], and its optical, positional, and geometric isomers, salts, and salts of isomers into schedule I. This action is based on a finding by the Administrator that the placement of this synthetic cannabinoid into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle, FUB-AMB.

DATES: This temporary scheduling order is effective November 3, 2017, until November 4, 2019. If this order is extended or made permanent, the DEA will publish a document in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement

Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

Section 201 of the Controlled Substances Act (CSA), 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling ¹ for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the

DEA. 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into schedule I of the CSA.2 The Acting Administrator transmitted notice of his intent to place FUB-AMB into schedule I on a temporary basis to the Assistant Secretary for Health by letter dated May 19, 2017. The Assistant Secretary responded to this notice by letter dated June 9, 2017, and advised that based on a review by the Food and Drug Administration (FDA), there were no active investigational new drug applications or approved new drug

¹ Though DEA has used the term "final order" with respect to temporary scheduling orders in the past, this notification adheres to the statutory language of 21 U.S.C. 811(h), which refers to a "temporary scheduling order." No substantive change is intended.

² As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the Department of Health and Human Service (HHS) in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

applications for FUB-AMB. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of FUB-AMB into schedule I of the CSA. The DEA has taken into consideration the Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). FUB-AMB is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for FUB-AMB under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the control of FUB-AMB in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, and as required by 21 U.S.C. 811(h)(1)(A), a notice of intent to temporarily schedule FUB-AMB was published in the Federal Register on September 11, 2017. 82 FR 42624.

To find that placing a substance temporarily into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA, 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

Available data and information for FUB-AMB, summarized below, indicate that this synthetic cannabinoid (SC) has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The DEA's three-factor analysis and the Assistant Secretary's June 9, 2017 letter are available in their entirety under the tab "Supporting Documents" of the public docket of this action at www.regulations.gov under FDMS Docket ID: DEA-2017-0010 (Docket Number DEA-472).

FUB-AMB

The illicit use of the synthetic cannabinoid (SC) methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate (Street names: FUB–AMB, MMB–FUBINACA,

AMB-FUBINACA) has dramatically increased over the past 12 months posing an imminent threat to public safety.

Synthetic Cannabinoids

SCs are substances synthesized in laboratories that mimic the biological effects of delta-9-tetrahydrocannabinol (THC), the main psychoactive ingredient in marijuana. It is believed that SCs were first introduced on the designer drug market in several European countries as "herbal incense" before the initial encounter in the United States by U.S. Customs and Border Protection (CBP) in November 2008. From 2009 to the present, misuse and abuse of SCs has increased in the United States with law enforcement encounters describing SCs applied onto plant material and in designer drug products intended for human consumption. It has been demonstrated that the substances and the associated designer drug products are abused for their psychoactive properties. With many generations of SCs having been encountered since 2009, FUB-AMB is one of the latest, and the abuse of these substances is negatively impacting communities

As observed by the DEA and CBP, SCs originate from foreign sources, such as China. Bulk powder substances are smuggled via common carrier into the United States and find their way to clandestine designer drug product manufacturing operations located in residential neighborhoods, garages, warehouses, and other similar destinations throughout the country. According to online discussion boards and law enforcement encounters, applying by spraying or mixing the SCs with plant material provides a vehicle for the most common route of administration—smoking (using a pipe, a water pipe, or rolling the drug-laced plant material in cigarette papers).

FUB-AMB has no accepted medical use in the United States. Use of this specific SC has been reported (see factor 6) to result in adverse effects in humans. Use of other SCs has resulted in signs of addiction and withdrawal and based on the similar pharmacological profile of FUB-AMB, it is believed that there will be similar observed adverse effects.

FUB-AMB is a SC that has pharmacological effects similar to the Schedule I hallucinogen THC and other temporarily and permanently controlled Schedule I synthetic cannabinoid substances. In addition, the misuse of FUB-AMB has been associated with multiple overdoses requiring emergency medical intervention (see factor 6). With no approved medical use and limited safety or toxicological information,

FUB-AMB has emerged on the designer drug market, and the abuse of this substance for its psychoactive properties is concerning.

Factor 4. History and Current Pattern of Abuse

Synthetic cannabinoids have been developed by researchers over the last 30 years as tools for investigating the endocannabinoid system, (e.g. determining CB1 and CB2 receptor activity). The first encounter of SCs within the United States occurred in November 2008 by CBP. Since then the popularity of SCs and their associated products has increased steadily as evidenced by law enforcement seizures, public health information, and media reports. FUB-AMB was originally encountered in 2014, but has since seen a large increase in its illicit use. The misuse of FUB-AMB has been associated with multiple overdoses involving emergency medical intervention.

Research and clinical reports have demonstrated that SCs are applied onto plant material so that the material may be smoked as users attempt to obtain a euphoric and/or psychoactive "high," believed to be similar to marijuana. Data gathered from a published study, and supplemented by discussions on Internet Web sites, demonstrate that these products are being abused mainly by smoking for their psychoactive properties. The adulterated products are marketed as "legal" alternatives to marijuana. In recent overdoses, FUB-AMB has been encountered in the form of herbal products, similar to the SCs that have been previously available.

The powder form of SČs is typically dissolved in solvents (e.g., acetone) before being applied to plant material or dissolved in a propellant intended for use in electronic cigarette devices. Law enforcement personnel have encountered various application methods including buckets or cement mixers in which plant material and one or more SCs are mixed together, as well as large areas where the plant material is spread out so that a dissolved SC mixture can be applied directly. Once mixed, the SC plant material is then allowed to dry before manufacturers package the product for distribution, ignoring any control mechanisms to prevent contamination or to ensure a consistent, uniform concentration of the substance in each package. Adverse health consequences may also occur from directly ingesting the drug during the manufacturing process. FUB-AMB, similar to other SCs, has been encountered in the form of dried leave or herbal blends.

The designer drug products laced with SCs, including FUB-AMB, are often sold under the guise of "herbal incense" or "potpourri," use various product names, and are routinely labeled "not for human consumption." Additionally, these products are marketed as a "legal high" or "legal alternative to marijuana" and are readily available over the Internet, in head shops, or sold in convenience stores. There is an incorrect assumption that these products are safe, that they are a synthetic form of marijuana, and that labeling these products as "not for human consumption" is a legal defense to criminal prosecution.

It is believed most abusers of SCs or SC-related products are smoking the product following application to plant material. Law enforcement has also begun to encounter new variations of SCs in liquid form. It is believed abusers have been applying the liquid to hookahs or "e-cigarettes," which allows the user to administer a vaporized liquid that can be inhaled.

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Factor 5. Scope, Duration and Significance of Abuse

SCs including FUB-AMB continue to be encountered on the illicit market regardless of scheduling actions that attempt to safeguard the public from the adverse effects and safety issues associated with these substances. Novel substances are encountered each month, differing only by small modifications intended to avoid prosecution while maintaining the pharmacological effects. Law enforcement and health care professionals continue to report the abuse of these substances and their associated products.

As described by the National Institute on Drug Abuse (NIDA), many substances being encountered in the illicit market, specifically SCs, have been available for years but have reentered the marketplace due to a renewed popularity. The threat of serious injury to the individual following the ingestion of FUB-AMB and other SCs persists.

The following information details information obtained through NFLIS ³ (queried on May 16, 2017), including dates of first encounter, exhibits/reports, and locations.

FUB-AMB: NFLIS-6,522 reports, first encountered in June 2014, locations include: Arizona, Arkansas, California, Colorado, Florida, Georgia, Idaho,

Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin and Wyoming.

Factor 6. What, if Any, Risk There Is to the Public Health

FUB-AMB has been identified in overdose cases attributed to its abuse. Adverse health effects reported from these incidents involving FUB-AMB have included: Nausea, persistent vomiting, agitation, altered mental status, seizures, convulsions, loss of consciousness, and cardiotoxicity. By sharing pharmacological similarities with Schedule I substances (Δ9-THC, JWH-018 and other temporarily and permanently controlled schedule I SCs), SCs pose a risk to the abuser. While these adverse effects have been shown by a variety of SCs, similar concerns remain regarding the welfare of the user as it relates to abuse of products laced with FUB-AMB. The risk of adverse health effects is further increased by the fact that similar products vary in the composition and concentration of SCs applied on the plant material.

Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information summarized above, the continued uncontrolled manufacture. distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of FUB-AMB poses an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for FUB-AMB in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for FUB-AMB indicate that this SC has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Administrator, through a letter dated May 19, 2017, notified the Assistant Secretary of the

DEA's intention to temporarily place FUB-AMB in Schedule I.

A notice of intent was subsequently published in the **Federal Register** on September 11, 2017. 82 FR 42624.

Conclusion

In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, and herein set forth the grounds for his determination that it is necessary to temporarily schedule methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate [FUB-AMB, MMB-FUBINACA, AMB-FUBINACA] into schedule I of the CSA to avoid an imminent hazard to the public safety.

Because the Administrator hereby finds it necessary to temporarily place this SC into schedule I of the CSA to avoid an imminent hazard to the public safety, this temporary order scheduling this substance is effective on the date of publication in the Federal Register, and is in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2).

The CSA sets forth specific criteria for scheduling a drug or other substance. Permanent scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The permanent scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the permanent scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Requirements for Handling

Upon the effective date of this final order, FUB-AMB will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances including the following:

1. Registration. Any person who handles (manufactures, distributes, reverse distributes, imports, exports,

³ The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States.

engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, FUB-AMB must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312, as of November 3, 2017. Any person who currently handles FUB-AMB and is not registered with the DEA, must submit an application for registration and may not continue to handle FUB-AMB as of November 3, 2017, unless the DEA has approved that application for registration. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of this substance in a manner not authorized by the CSA on or after November 3, 2017 is unlawful and those in possession of any quantity of this substance may be subject to prosecution pursuant to the

2. Disposal of stocks. Any person who does not desire or is not able to obtain a schedule I registration to handle FUBAMB must surrender all quantities of currently held FUBAMB.

3. Security. FUB—AMB is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71—1301.93, as of November 3, 2017.

4. Labeling and Packaging. All labels, labeling, and packaging for commercial containers of FUB-AMB must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302. Current DEA registrants shall have 30 calendar days from November 3, 2017, to comply with all labeling and

packaging requirements. 5. Inventory. Every DEA registrant who possesses any quantity of FUB-AMB on the effective date of this order, must take an inventory of all stocks of this substance on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including FUB-AMB) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. Records. All DEA registrants must maintain records with respect to FUB– AMB pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304 and 1312, 1317 and § 1307.11. Current DEA registrants authorized to handle FUB-AMB shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

7. Reports. All DEA registrants who manufacture or distribute FUB—AMB must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312 as of November 3, 2017.

8. Order Forms. All DEA registrants who distribute FUB-AMB must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of November 3, 2017.

9. Importation and Exportation. All importation and exportation of FUB—AMB must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of November 3, 2017.

10. Quota. Only DEA registered manufacturers may manufacture FUB—AMB in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of November 3, 2017.

11. Liability. Any activity involving FUB-AMB not authorized by, or in violation of the CSA, occurring as of November 3, 2017, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of the Administrative Procedure Act (APA) at 5 U.S.C. 553, do not apply to this temporary scheduling action. In the alternative, even assuming that this action might be subject to 5 U.S.C. 553, the Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Further, the DEA believes that this temporary scheduling action is not a "rule" as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget.

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. However, if this were a rule, pursuant to the CRA, "any rule for which an agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the federal agency promulgating the rule determines." 5 U.S.C. 808(2). It is in the public interest to schedule this substance immediately to avoid an imminent hazard to the public safety. This temporary scheduling action is taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h) exempts the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie 21 U.S.C. 811(h), that is, the need to move quickly to place this substance into schedule I because it poses an imminent hazard to public safety, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, this order

shall take effect immediately upon its

publication.

The DEA has submitted a copy of this temporary order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act), 5 U.S.C. 801–808, because as noted above, this action is an order, not a rule.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. Amend § 1308.11 by adding paragraph (h)(18) to read as follows:

§ 1308.11 Schedule I.

(h) * * *

(18) methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: FUB–AMB, MMB–FUBINACA, AMB–FUBINACA) (7021)

Dated: October 27, 2017.

Robert W. Patterson,

Acting Administrator.

[FR Doc. 2017–24010 Filed 11–2–17; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2017-0979]

Drawbridge Operation Regulation; Kent Island Narrows, Grasonville, MD

AGENCY: Coast Guard, DHS. **ACTION:** Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the U.S. Route 50/ 301 (Kent Narrows) Bridge across the Kent Island Narrows, mile 1.0, at Grasonville, MD. The deviation is necessary to facilitate a routine inspection. This deviation allows the bridge to remain in the closed-tonavigation position.

DATES: This deviation is effective from 9 a.m. on November 7, 2017, to 3 p.m. on November 9, 2017.

ADDRESSES: The docket for this deviation [USCG—2017—0979] is available at http://www.regulations.gov. Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Mickey Sanders, Bridge Administration Branch Fifth District, Coast Guard; telephone (757) 398–6587, email Mickey.D.Sanders2@uscg.mil.

SUPPLEMENTARY INFORMATION: The Maryland State Highway Administration, owner and operator of the U.S. Route 50/301 (Kent Narrows) Bridge across the Kent Island Narrows, mile 1.0, at Grasonville, MD, has requested a temporary deviation from the current operating schedule to accommodate a routine inspection. The bridge has a vertical clearance of 18 feet above mean high water (MHW) in the closed position.

The current operating schedule is set out in 33 CFR 117.561. Under this temporary deviation, the bridge will require 30 minutes advanced notice to open from 9 a.m. on November 7, 2017, to 3 p.m. on November 9, 2017.

The Kent Island Narrows is used by a variety of vessels including small commercial vessels, recreational vessels and tug and barge traffic. The Coast Guard has carefully coordinated the restrictions with waterway users in publishing this temporary deviation.

Vessels able to pass through the bridge in the closed position may do so if at least 15 minutes notice is given. The bridge will be able to open for emergencies and there is no immediate alternate route for vessels unable to pass through the bridge in the closed position. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notice to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by this temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of this effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: October 31, 2017.

Hal R. Pitts,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2017–24028 Filed 11–2–17; 8:45 am] BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Parts 61 and 62 RIN 2900-AQ07

Homeless Veterans

AGENCY: Department of Veterans Affairs. **ACTION:** Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its regulations that govern homeless veterans to conform to recent statutory requirements. VA is amending the definition of homeless veterans by including veterans who would otherwise be ineligible to receive certain benefits because of their length of service or type of discharge from the Armed Forces. This rule will also increase the payment of per diem in cases where homeless veterans are placed in transitional housing that will become permanent housing. This final rule is an essential part of VA's attempts to eliminate homelessness among the veteran population.

DATES: This final rule is effective December 4, 2017.

FOR FURTHER INFORMATION CONTACT: Guy Liedke, guy.liedke@va.gov, Program Analyst, Grant/Per Diem Program, (673/GPD), VA National Grant and Per Diem Program Office, 10770 N. 46th Street, Suite C–200, Tampa, FL 33617, (877) 332–0334. (This is a toll-free number.)

SUPPLEMENTARY INFORMATION: In an effort to reduce homelessness in the veteran population, Congress has required VA to expand its definition of veteran as it applies to benefits for homeless veterans. See Public Law 114-315, sec. 701, 702, and 703 (Dec. 16, 2016). This new definition will remove restrictions on length of military service for a homeless veteran receiving certain benefits from VA, as well as authorize certain benefits for veterans with types of discharges from the Armed Forces that would normally bar an individual from receiving VA benefits. Congress also required VA to increase the per diem payments for transitional housing assistance that will become permanent housing for homeless veterans. See Public Law 114-315, sec. 711 (Dec. 16,

SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

Placement of Four Synthetic Cannabinoids into Schedule I for Controlled Substances

Whereas, pursuant to S.C. Code Section 44-53-160(C), the S.C. Board of Health and Environmental Control (Board) is authorized to designate a substance as a controlled substance by scheduling it in accordance with an order effecting federal scheduling as a controlled substance; and

Whereas, the U.S. Drug Enforcement Administration (DEA) published on February 10, 2014, a final order temporarily placing four synthetic cannabinoids, Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC); Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22); *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA); and *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA), into Schedule I of the Controlled Substances Act (CSA) effective on the date of publication. F.R. Volume 79, Number 27, pp. 7577-7582; http://www.gpo.gov/fdsys/pkg/FR-2014-02-10/pdf/2014-02848.pdf; and

Whereas, the DEA final rule states that available data and information indicate that these four synthetic cannabinoids have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision; and

Whereas, the Board anticipates that the DEA will publish its final order scheduling the four synthetic cannabinoids into Schedule I as soon as possible in order to preempt the continued distribution of these illicit drugs;

Now, therefore, the following four substances are hereby designated and added as Schedule I Controlled Substances pursuant to the S.C. Controlled Substances Act, effective immediately:

- (1) Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC),
- (2) Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22),
- (3) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA), and

(4) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA).

February 27, 2014 Columbia, South Carolina Allen Amsler, Chairman

S.C. Board of Health and Environmental Control