

SUMMARY SHEET  
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

February 13, 2020

- ( ) ACTION/DECISION  
( X ) INFORMATION

- I. TITLE:** Health Regulation Administrative and Consent Orders.
- II. SUBJECT:** Health Regulation Administrative Orders and Consent Orders for the period of December 1, 2019 through December 31, 2019.
- III. FACTS:** For the period of December 1, 2019 through December 31, 2019, Health Regulation reports 3 Consent Orders totaling \$33,600 in assessed monetary penalties. No Administrative Orders or Emergency Suspension Orders were executed during the reporting period.

Health Regulation Bureau	Facility, Service, Provider, or Equipment Type	Administrative Orders	Consent Orders	Emergency Suspension Orders	Assessed Penalties
Health Facilities Licensing	Nursing Home	0	1	0	\$18,300
	Community Residential Care Facility	0	1	0	\$4,300
Radiological Health	Radioactive Materials Industrial Facility	0	1	0	\$11,000
<b>TOTAL</b>		<b>0</b>	<b>3</b>	<b>0</b>	<b>\$33,600</b>

Submitted By:

*Gwendolyn C. Thompson*

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Gwen C. Thompson  
Interim Director  
Health Regulation

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

February 13, 2020

**Bureau of Health Facilities Licensing**

Facility Type	Total # of Licensed Facilities	Total # of Licensed Beds
Nursing Home	195	20,555

**1. Brian Center of Nursing Care-St. Andrews – Columbia, SC**

Inspections and Investigations: The Department conducted ten complaint investigations between 2018 and 2019, as well as two routine inspections within the same period, and found several repeat regulatory violations.

Violations: The Department found that the facility had a total of 29 violations during its 2018 investigations and inspections, as well as a total of 27 violations during its 2019 investigations and inspections. The violations were related to, among other things, improper storage of medication and supplies, failure to properly secure oxygen tanks, failure to have complete staff records regarding tuberculosis skin tests and vaccinations, damaged or unlabeled medication cabinets, incomplete records of medication administration, failure to ensure nursing staff were currently licensed to practice nursing in South Carolina and had valid CPR certificates, failure to have updated staff and private sitter training records, and failure to administer medications in accordance with orders of an attending physician.

Enforcement Action: The parties conducted an enforcement conference and agreed to resolve the matter by consent order. In December 2019, the parties executed a consent order imposing a civil monetary penalty of \$18,300 against the facility. The facility was required to pay \$10,900 of the assessed penalty in two consecutive monthly payments of \$5,450, with the first payment due within 30 days, and the second payment due within 60 days, of executing the Consent Order. The remaining \$7,400 of the penalty will be held in abeyance for six months. The facility has made both required payments. The Department will also conduct a follow-up inspection of the facility in February 2020.

Prior Actions: None in the past five years.

Facility Type	Total # of Licensed Facilities	Total # of Licensed Beds
Community Residential Care Facility	505	21,901

**2. Langit’s Assisted Living Facility – North Charleston, SC**

Inspections and Investigations: During the Department’s emergency response efforts for Hurricane Dorian, the Department found that the facility did not evacuate in accordance with the Governor’s Executive Order issued in September 2019 that required a mandatory medical evacuation of healthcare facilities located in evacuation zones.

Violations: The Department found that the facility failed to evacuate all of its residents in a timely matter. While eight residents had been properly evacuated to another residential care facility in anticipation of Hurricane Dorian, the remaining 40 residents were still present at the facility when a Department representative contacted the facility on September 4, 2019, in order to inquire on its evacuation status. The facility had secured transport to evacuate that morning, but failed to assemble the residents in time before the transportation vehicle left. The facility had not found an alternative transportation for its 40 remaining residents. The Department had to assist the facility in acquiring an alternate transportation company to safely evacuate the residents.

Enforcement Action: The parties agreed to resolve the matter by consent order. In December 2019, the parties executed a consent order imposing a civil monetary penalty of \$4,300 against the facility. The facility was required to pay \$2,150 of the assessed penalty in two consecutive monthly payments of \$1,075, with the first payment due within 30 days, and the second payment due within 60 days, of executing the Consent Order. The remaining \$2,150 of the penalty will be held in abeyance for six months. The facility has made the first required monthly payment.

Prior Actions: None in the past five years.

### **Bureau of Radiological Health**

Facility Type	Total # of Licensed Facilities
Radioactive Materials Industrial Facility	330

#### **15. Professional Service Industries, Inc. – Columbia, SC**

Inspections and Investigations: The Department conducted an investigation in January 2019 and found that the licensee had both regulatory and South Carolina Radioactive Material License violations.

Violations: The Department found that the licensee violated the Radioactive Materials Regulation by allowing untrained and unauthorized individuals to have access to licensed materials stored in a controlled area. Moreover, the licensee violated special conditions within the Radioactive Materials License, including having untrained and unsupervised individuals be in the physical presence of radioactive materials, as well as failing to properly maintain utilization logs for gauging devices containing radioactive materials.

Enforcement Action: The parties agreed to resolve the matter by consent order. In December 2019, the parties executed a consent order imposing a \$11,000 civil monetary penalty against the licensee. The licensee was required to pay the monetary penalty in full within 30 days of executing the Consent Order. The licensee has made the required payment.

Prior Actions: None in the past five years.

SUMMARY SHEET  
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL  
February 13, 2020

           ACTION/DECISION

  X   INFORMATION

1. **TITLE:** Administrative and Consent Orders issued by the Office of Environmental Affairs.
2. **SUBJECT:** Administrative and Consent Orders issued by the Office of Environmental Affairs during the period December 1, 2019, through December 31, 2019.
3. **FACTS:** For the reporting period of December 1, 2019, through December 31, 2019, the Office of Environmental Affairs issued eighty-one (81) Consent Orders with total assessed civil penalties in the amount of one hundred seventeen thousand, nine hundred forty dollars (\$117,940.00). Also, five (5) Administrative Orders were reported during this period with total assessed civil penalties in the amount of sixty-seven thousand, six hundred four dollars (\$67,604.00).

Bureau and Program Area	Administrative Orders	Assessed Penalties	Consent Orders	Assessed Penalties
<b>Land and Waste Management</b>				
UST Program	4	\$50,604.00	5	\$5,890.00
Aboveground Tanks	0	0	0	0
Solid Waste	1	\$17,000.00	2	\$2,600.00
Hazardous Waste	0	0	0	0
Infectious Waste	0	0	0	0
Mining	0	0	1	\$1,000.00
<b>SUBTOTAL</b>	<b>5</b>	<b>\$67,604.00</b>	<b>8</b>	<b>\$9,490.00</b>
<b>Water</b>				
Recreational Water	0	0	15	\$17,000.00
Drinking Water	0	0	1	\$0.00
Water Pollution	0	0	7	\$36,500.00
Dam Safety	0	0	0	0
<b>SUBTOTAL</b>	<b>0</b>	<b>0</b>	<b>23</b>	<b>\$53,500.00</b>
<b>Air Quality</b>				
<b>SUBTOTAL</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Environmental Health Services</b>				
Food Safety	0	0	50	\$54,950.00
Onsite Wastewater	0	0	0	0
<b>SUBTOTAL</b>	<b>0</b>	<b>0</b>	<b>50</b>	<b>\$54,950.00</b>
<b>OCRM</b>				
<b>SUBTOTAL</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>TOTAL</b>	<b>5</b>	<b>\$67,604.00</b>	<b>81</b>	<b>\$117,940.00</b>

Submitted by:

*Myra C. Reece*

Myra C. Reece  
Director of Environmental Affairs

**ENVIRONMENTAL AFFAIRS ENFORCEMENT REPORT  
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL  
February 13, 2020**

**BUREAU OF LAND AND WASTE MANAGEMENT**

**Underground Storage Tank Enforcement**

- 1)     Order Type and Number:             Administrative Order 19-0354-UST  
       Order Date:                         November 7, 2019  
       Individual/Entity:                 **Vikri Investments, LLC**  
       Facility:                             J-Express  
       Location:                             2705 East Cherokee Street  
  Blacksburg, SC 29702  
  
       Mailing Address:                     Same  
       County:                               Cherokee  
       Previous Orders:                     None  
       Permit/ID Number:                 19256  
       Violations Cited:                 The State Underground Petroleum  
  Environmental Response Bank Act of 1988, S.C. Code Ann. § 44-2-10 *et seq.*  
  (2018) (SUPERB Act); and South Carolina Underground Storage Tank Control  
  Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.31(a), 280.34(c), 2380.40(a),  
  280.41(b)(1)(i)(B), 280.44(a), 280.45(b)(1), 280.93(a), 280.110(c), 280.242(b)(3),  
  280.242(b)(4), 280.234(c), 280.245 (2012 & Supp. 2018).

Summary: Vikri Investments, LLC (Individual/Entity) owns and operates underground storage tanks in Blacksburg, South Carolina. On May 19, 2018, the Department issued a Notice of Alleged Violation (NOAV) because there was no financial responsibility documentation on file with the Department. On August 1, 2018, the Department issued a NOAV because annual tank registration fees (ATRFs) for fiscal year 2019 were past due. On December 28, 2018, the Department issued a NOAV because: the Class A/B operator log had not been properly filled out; there was no list of trained Class C Operators on site; proper release detection using an automatic tank gauge had not been performed; the corrosion protection system had not been properly maintained; there was no line tightness test results available for review; and there was no line leak detector test results available for review. On August 2, 2019, the Department issued a NOAV because ATRFs for fiscal year 2020 were past due. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to demonstrate financial responsibility for an UST system and failed to provide evidence of financial assurance to the Department upon request; failed to validate that monthly requirements had been performed; failed to train Class C Operators; failed to conduct proper release detection using an automatic tank gauge; failed to maintain and operate a corrosion protection system; failed to conduct an annual line tightness test; failed to

conduct annual testing of automatic line leak detectors; and failed to pay ATRFs.

Action: The Individual/Entity is required to: submit a completed Certificate of Financial Responsibility form and provide evidence of financial assurance; pay annual underground tank registration fees and associated late fees for fiscal years 2019 and 2020 in the amount of two thousand, four hundred twenty dollars (\$2,420.00); submit a completed Class A/B Operator log and a list of trained Class C Operators; submit the most current twelve (12) months of ATG records or tank tightness test results for all underground storage tanks (USTs); submit proof that water has been removed from the regular, diesel and premium submersible turbine pump pits; submit line tightness test results for the regular, diesel, and premium USTs; submit line leak detector function check test results for the regular, diesel, and premium USTs; and pay a civil penalty in the amount of sixteen thousand, three hundred fifty dollars (**\$16,350.00**).

2) Order Type and Number: Administrative Order 19-0162-UST  
Order Date: December 3, 2019  
Individual/Entity: **Sean P. Kilcoyne**  
Facility: Edisto River Company  
Location: 9503 Freedom Road  
Branchville, SC 29432  
Mailing Address: Same  
County: Bamberg  
Previous Orders: None  
Permit/ID Number: 13072  
Violations Cited: The State Underground Petroleum  
Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann., § 44-  
2-10 et seq. (2018); and South Carolina Underground Storage Tank Control  
Regulation, 7 S.C. Code Ann., Regs. 61-92.280.93(a) and 280.110(c) (2018).

Summary: Sean P. Kilcoyne (Individual/Entity) owns underground storage tanks (USTs) located in Branchville, South Carolina. On April 1, 2019, and August 6, 2019, the Department issued Notices of Alleged Violations because the Department had no evidence of financial assurance on file and the annual tank registration fees and associated late fees for fiscal year 2020 had not been paid. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Control Regulation as follows: failed to pay annual tank registration fees and associated late fees for fiscal year 2020 and failure to complete a Certificate of Financial Responsibility form and submit evidence of financial assurance to the Department.

Action: The Individual/Entity is required to: pay annual underground tank registration fees and associated late fees for fiscal year 2020 in the amount of one thousand, eight hundred fifteen dollars (\$1,815.00); submit a completed Certificate of Financial Responsibility form and evidence of financial assurance to the Department; and pay a civil penalty in the amount of five thousand, six hundred fifty (**\$5,650.00**).

- 3)     Order Type and Number:           Administrative Order 19-0377-UST  
       Order Date:                    December 17, 2019  
       Individual/Entity:            **Donald Kenneth Graham**  
       Facility:                      Sam's Grocery & Grill  
       Location:                      1969 South Highway 501  
  Marion, SC 29571  
       Mailing Address:            546 Shannon Road  
  Marion, SC 29571  
       County:                        Marion  
       Previous Orders:             None  
       Permit/ID Number:          06208  
       Violations Cited:           The State Underground Petroleum  
       Environmental Response Bank Act of 1988, S.C. Code Ann. § 44-2-10 *et seq.*  
       (2018) (SUPERB Act); and South Carolina Underground Storage Tank Control  
       Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.70(c), 280.93(a), and 280.110(c)  
       (2012 & Supp. 2018).

Summary: Donald Kenneth Graham (Individual/Entity) owns and operates underground storage tanks in Marion, South Carolina. On August 2, 2019, the Department issued a Notice of Alleged Violation (NOAV) because annual tank registration fees for fiscal year 2020 were past due. On September 11, 2019, the Department conducted a file review and noted: annual underground tank registration fees for fiscal years 2016, 2018, and 2019, had not been paid; there was no financial responsibility documentation on file with the Department; and the underground storage tank (UST) corrosion protection requirements had not been met. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to permanently close a UST system that has been temporarily out of service for greater than twelve (12) months and does not meet current corrosion protection standards; failed to demonstrate financial responsibility for an UST system; and failed to provide evidence of financial assurance to the Department upon request; and failed to pay annual underground tank registration fees.

Action: The Individual/Entity is required to: submit a completed Certificate of Financial Responsibility form and provide evidence of financial assurance; pay annual underground tank registration fees and associated late fees for fiscal years 2016, 2018, 2019, and 2020, in the amount of six thousand, seventy-five dollars (\$6,075.00); submit a completed Tank and Sludge Disposal Form for the permanent closure of the UST; submit an UST Closure and Assessment Report; and pay a civil penalty in the amount of twenty-one thousand, seven hundred fifty-four dollars (**\$21,754.00**).

- 4)     Order Type and Number:           Administrative Order 19-0379-UST  
       Order Date:                    December 17, 2019  
       Individual/Entity:            **Timothy Letman & John Norman**  
       Facility:                      Mount Carmel Auto & Tire Center  
       Location:                      3728 SC 81

Mailing Address: Mount Carmel, SC 29835  
301 Bedford Place  
McCormick, SC 29835

County: McCormick

Previous Orders: None

Permit/ID Number: 06404

Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988, S.C. Code Ann. § 44-2-10 et seq. (2018) (SUPERB Act); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.93(a), 280.110(c), and 280.243(b) (2012 & Supp. 2018).

Summary: Timothy Letman & John Norman (Individual/Entity) own and operate underground storage tanks in McCormick, South Carolina. On December 18, 2017, the Department issued a Notice of Alleged Violation (NOAV) because there was no financial responsibility documentation on file with the Department. On December 21, 2017, the Department issued a NOAV because there was no trained Class A/B operator on file with the Department. On August 3, 2018, the Department issued a NOAV because annual underground tank registration fees for fiscal year 2019 were past due. On August 1, 2019, the Department issued a NOAV because annual underground tank registration fees for fiscal year 2020 were past due. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to demonstrate financial responsibility for an UST system; failed to provide evidence of financial assurance to the Department upon request; failed to have a properly trained Class A/B operator within thirty (30) days of assuming business; and failed to pay annual underground tank registration fees.

Action: The Individual/Entity is required to: submit a completed Certificate of Financial Responsibility form and provide evidence of financial assurance; pay annual underground tank registration fees and associated late fees for fiscal years 2019 and 2020 in the amount of two thousand, four hundred twenty dollars (\$2,420.00); submit proof that a Class A/B operator has been trained and designated for the Facility; and pay a civil penalty in the amount of six thousand, eight hundred fifty dollars (**\$6,850.00**).

5) Order Type and Number: Consent Order 19-0320-UST

Order Date: December 3, 2019

Individual/Entity: **Juanita Gibson**

Facility: Pitts Quick Stop

Location: 15973 Highway 101 South  
Gray Court, SC 29645

Mailing Address: 405 Cooper Bridge Road  
Fountain Inn, SC 29644

County: Laurens

Previous Orders: None

Permit/ID Number: 16878



Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 et seq. (2018).

Summary: Juanita Gibson (Individual/Entity), owns and operates an underground storage tank located in Gray Court, South Carolina. On August 2, 2019, the Department issued a Notice of Alleged Violation because Juanita Gibson had not paid annual tank registration fees for fiscal year 2020. The Individual/Entity has violated the SUPERB Act as follows: failure to pay annual tank registration fees.

Action: The Individual/Entity is required to: pay annual tank registration fees and associated late fees for fiscal year 2020 in the amount of one thousand, two hundred ten dollars (\$1,210.00) and pay a civil penalty in the amount of two hundred forty dollars (**\$240.00**).

6) Order Type and Number: Consent Order 19-0382-UST  
Order Date: December 5, 2019  
Individual/Entity: STC, Inc.  
Facility: Richland County School District 1  
Maintenance Facility  
Location: 220 Wayne Street  
Columbia, SC 29201  
Mailing Address: 7108 Augusta Road, Suite B  
Piedmont, SC 29673  
County: Richland  
Previous Orders: None  
Permit/ID Number: 07345  
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann., § 44-2-10 et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92.280.10(d) (2018).

Summary: STC, Inc. (Individual/Entity) supplies underground storage tanks (USTs) with fuel in South Carolina. On September 19, 2019, the Department issued a Notice of Alleged Violation because fuel was delivered into USTs in which the owner did not have a valid registration. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Control Regulations as follows: introduced regulated substances into USTs for which the owner does not hold a currently valid registration.

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

7) Order Type and Number: Consent Order 19-0135-UST  
Order Date: December 10, 2019  
Individual/Entity: **Charles D. Strickland**  
Facility: City Foods  
Location: 438 North Main Street  
Darlington, SC 29532  
Mailing Address: Same  
County: Darlington  
Previous Orders: none  
Permit/ID Number: 02751  
Violations Cited: The State Underground Petroleum  
Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann., § 44-  
2-60(A) (2018); and South Carolina Underground Storage Tank Control  
Regulation, 7 S.C. Code Ann., Regs. 61-92.31(c), 280.34(c), 280.40(a), 280.44(a)  
280.45(b)(1), 280.50, 280.52, 280.242(b)(3), and 280.242(b)(4) (2012 & Supp.  
2018).

Summary: Charles D. Strickland (Individual/Entity) owns underground storage tanks (USTs) located in Darlington, South Carolina. On April 3, 2019, the Department issued a Notice of Alleged Violation because current automatic tank gauge (ATG) records were not available at the time of inspection; monthly monitoring of pressurized piping was not conducted; annual line leak detector test results were not available at the time of inspection; the cathodic protection system was not tested every 60 days; monthly site visits were not performed; quarterly site visits were not performed; a suspected release was not confirmed and reported; and, a registration certificate was not displayed. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Control Regulation as follows: failed to provide records to the Department upon request and failed to maintain records for one year; failed to provide an adequate release detection method and conduct proper release detection for an UST system using ATG; failed to perform monthly monitoring of the pressurized piping; failed to perform annual testing of line leak detectors; failed to operate continuously and maintain a cathodic protection system; failed to submit Class A/B Operator logs; failed to provide a list of Class C operators; failed to investigate and confirm a suspected release; and failed to display a valid registration certificate.

Action: The Individual/Entity is required to submit: evidence that the regular UST has been, repaired and retested; a site check around the regular UST; evidence that a Class A/B operator log is being kept; evidence that a current registration certificate is displayed in a conspicuous location; evidence that a rectifier log is being kept; evidence that the USTs contain less than one inch (1) of liquid; and, payment of a civil penalty in the amount of three thousand, six hundred fifty dollars (**\$3,650.00**).

8)     Order Type and Number:                     Consent Order 19-0375-UST  
       Order Date:                                 December 17, 2019  
       Individual/Entity:                     **Emoray R. Waiters d.b.a. Prestige Cycles**  
       Facility:                                 Prestige Cycles Sales & Service  
       Location:                                 2996 Flat Creek Road  
  Lancaster, SC  
       Mailing Address:                     2938 Flat Creek Road  
  Lancaster, SC 29720  
  
       County:                                 Lancaster  
       Previous Orders:                     None  
       Permit/ID Number:                 05523  
       Violations Cited:                     The State Underground Petroleum  
       Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-  
       2-10 et seq. (2018), and the South Carolina Underground Storage Tank Control  
       Regulations, 7 S.C. Code Ann. Regs. 61-92.280.70(a), 280.93(a), and 280.110(c)  
       (2012 & Supp. 2018).

Summary: Emoray R. Waiters d.b.a. Prestige Cycles (Individual/Entity), owns and operates an underground storage tank located in Lancaster, South Carolina. On October 18, 2019 the Department issued a Notice of Alleged Violation/Enforcement Conference because Emoray R. Waiters had not paid annual tank registration fees for fiscal years 2018, 2019, and 2020; did not have current financial responsibility documentation on file with the Department; and had greater than one (1) inch of residue in an extended out-of-use UST. The Individual/Entity has violated the SUPERB Act and the S.C. Underground Storage Tank Control Regulation as follows: failed to pay annual tank registration fees; failed to submit evidence of financial assurance to the Department upon request; and failed to maintain appropriate release detection on a temporarily closed UST.

Action: The Individual/Entity is required to: pay annual tank registration fees and associated late fees for fiscal years 2018 through 2020 in the amount of five thousand, two hundred ninety five dollars (5,295.00) in accordance with a promissory note; submit a completed Certificate of Financial Responsibility form and submit evidence of financial assurance; and submit proof that the extended out-of-use tank contains less than one (1) inch of residue or submit current tank tightness, line tightness, and light leak detector test results. The Department assessed a civil penalty in the amount of three thousand, eight hundred seventy-five dollars (\$3,875.00); however, the Department agrees to **suspend the civil penalty** in the amount of **\$3,875.00** pending compliance with the Order.

9)     Order Type and Number:                     Consent Order 19-0485-UST  
       Order Date:                                 December 20, 2019  
       Individual/Entity:                     **City of Columbia**  
       Facility:                                 Columbia Fire Dept Industrial Park  
       Location:                                 2740 The Boulevard  
  Columbia, SC  
       Mailing Address:                     2910 Colonial Drive

Columbia, SC 29203  
County: Richland  
Previous Orders: None  
Permit/ID Number: 16767  
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. Code Ann. § 44-2-10 et seq. (2018), and the South Carolina Underground Storage Tank Control Regulations, 7 S.C. Code Ann., Regs. 61-92.280.20(c)(1)(ii) (2012 & Supp. 2018).

Summary: City of Columbia (Individual/Entity), owns underground storage tanks located in Columbia, South Carolina. On November 11, 2019, the Department issued a Notice of Alleged Violation to City of Columbia because a tank gauging stick was found in the drop tube shut off device of the 10,000-gallon diesel UST. The Individual/Entity has violated the SUPERB Act and the S.C. 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**).

### **Solid Waste Enforcement**

10) Order Type and Number: Administrative Order 19-06-SW  
Order Date: November 14, 2019  
Individual/Entity: **David Henderson**  
Facility: TMS # 053-00-00-018.001  
Location: 3714 Cowpens Pacolet Road  
Spartanburg, SC  
Mailing Address: 521 Ray Blackley Road  
Inman, SC 29349  
County: Cherokee  
Previous Orders: None  
Permit/ID Number: None  
Violations Cited: South Carolina Solid Waste Policy and Management Act of 1991 (Act), Solid Waste Management: Solid Waste Landfills and Structural Fill Regulation (Regulation), R.61-107.19, Part IV.A.3

Summary: David N. Henderson (Individual/Entity), is responsible for operating an unpermitted structural fill in Cherokee County, South Carolina. The Department conducted inspections on September 28, 2018, October 1, 2018, October 30, 2018, November 2, 2018, December 17, 2018, January 15, 2019, and February 13, 2019, and observed that construction and demolition debris had been dumped at the Site in an effort to fill in a ditch or low-lying area. The Individual/Entity has violated the South Carolina Solid Waste Policy and Management Act, and the Solid Waste Management: Solid Waste

Landfills and Structural Fill Regulation as follows: failed to obtain a permit from the Department prior to construction and operation of a Class Two landfill.

Action: The Individual/Entity is required to: complete closure activities of the Site and pay a civil penalty in the amount of seventeen thousand dollars (**\$17,000.00**).

- 11) Order Type and Number: Consent Order 19-24-SW  
Order Date: December 5, 2019  
Individual/Entity: **Williamsburg County Office**  
Facility: Williamsburg County Class II Landfill  
Location: 564 Old Gapway Road  
Salters, SC 29590  
Mailing Address: Same  
County: Williamsburg  
Previous Orders: None  
Permit/ID Number: 451001-1201  
Violations Cited: South Carolina Solid Waste Policy and Management Act of 1991, S.C. Code Ann. §§ 44-96-10 et seq. (2002 & Supp. 2018); Solid Waste Management: Solid Waste Landfills and Structural Fill Regulation, R.61-107.19 (2012) Part IV.C.16(c)(2); Class II Landfill Facility Permit number 451001-1201, A.5.

Summary: Williamsburg County Office (Individual/Entity), operates a Class II Landfill in Salters, South Carolina. The Individual/Entity violated the South Carolina Solid Waste Policy and Management Act, the Solid Waste Management: Solid Waste Landfills and Structural Fill Regulation, and the Permit as follows: failed to submit the annual report for fiscal year 2019.

Action: The Individual/Entity is required to: submit the annual report for fiscal year 2019 and pay a civil penalty in the amount of five hundred dollars (**\$500.00**).

- 12) Order Type and Number: Consent Order 19-30-SW  
Order Date: December 17, 2019  
Individual/Entity: **Dargan Dewey Haddock**  
Facility: Henry Road  
Location: TMS #45-472-010  
Mailing Address: 404 Rice Bluff Road  
Pawleys Island, SC 29585  
County: Williamsburg  
Previous Orders: None  
Permit/ID Number: N/A  
Violations Cited: South Carolina Solid Waste Policy and Management Act of 1991, S.C. Code Ann. §§ 44-96-10 et seq. (2002 & Supp.

2018); and Solid Waste Management: Solid Waste Landfills and Structural Fill Regulation, R.61-107.19 (2012) Part I.A.8 and Part IV.A.3.

Summary: Dargan Dewey Haddock (Individual/Entity), operated a Class II Landfill in Hopewell, South Carolina. The Individual/Entity violated the South Carolina Solid Waste Policy and Management Act and the Solid Waste Management: Solid Waste Landfills and Structural Fill Regulation as follows: failed to obtain a permit prior to operating a Class II landfill.

Action: The Individual/Entity is required to: remove all solid waste from the Site; submit disposal receipts as proof of proper disposal; and pay a civil penalty in the amount of two thousand, one hundred dollars (\$2,100.00) in accordance with a promissory note.

### **Mining Enforcement**

13) Order Type and Number: Consent Order 19-07-MSWM/19-19-SW  
Order Date: December 05, 2019  
Individual/Entity: **Howard Grading & Construction, Inc.**  
Facility: N/A  
Location: Turpin Road  
Inman, SC  
Mailing Address: 257 Burnett Road  
Inman, SC 29349  
County: Spartanburg  
Previous Orders: None  
Permit/ID Number: None  
Violations Cited: South Carolina Mining Act (2008 & Supp. 2015), the Mining Regulation, Section 20 (Supp. 2012), the South Carolina Solid Waste Policy and Management Act of 1991 (Act), and the Solid Waste Management: Solid Waste Landfills and Structural Fill Regulation (Regulation), R.61-107.19, Part I.A.8, Part I.B.53, and Part IV.A.3.

Summary: Howard Grading & Construction, Inc. (Individual/Entity), is responsible for operating an unpermitted mine in Spartanburg County, South Carolina. The Department conducted an inspection on May 7, 2019 and observed the following: that the land had been disturbed in a manner consistent with mining activities; malfunctioning silt fences; a retention pond full of sediment, and multiple piles of asphalt and concrete deposited around the disturbed area. The Individual/Entity has violated the South Carolina Mining Act, the Mining Regulation, South Carolina Solid Waste Policy and Management Act, and the Solid Waste Management: Solid Waste Landfills and Structural Fill Regulation as follows: failed to obtain a permit from the Department prior to engaging in mining; and failed to obtain a permit from the Department prior to construction and operation of a Class Two landfill.

Action: The Individual/Entity is required to: cease all mining activities and acceptance of solid waste debris; remove all concrete from the Site and submit disposal/recycle receipts to the Department; submit documentation to apply for a mining permit **or** complete closure activities of the Site; and, pay a civil penalty in the amount of one thousand dollars (**\$1,000.00**).

## BUREAU OF WATER

### Recreational Waters Enforcement

14) Order Type and Number: Consent Order 19-274-RW  
Order Date: December 2, 2019  
Individual/Entity: **Fairflo Hotel, LLC**  
Facility: Fairfield Inn and Suites  
Location: 501 Woody Jones Boulevard  
Florence, SC 29501  
Mailing Address: 1493 Hoffmeyer Road, Suite C  
Florence, SC 29501  
County: Florence  
Previous Orders: None  
Permit/ID Number: 21-1027B  
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Fairflo Hotel, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On March 29, 2019, June 26, 2019, and October 2, 2019, 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 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; the chlorine level was not within the acceptable range of water quality standards; the emergency notification device was not operational; and, a handrail was not tight and secure.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of two thousand, forty dollars (**\$2,040.00**). The civil penalty has been paid.

15) Order Type and Number: Consent Order 19-275-RW  
Order Date: December 2, 2019  
Individual/Entity: **Hurl Rock Motel, Inc.**  
Facility: Gazebo Inn  
Location: 1607 South Ocean Boulevard  
Myrtle Beach, SC 29577

Mailing Address: Same  
County: Horry  
Previous Orders: None  
Permit/ID Number: 26-J79-1  
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Hurl Rock Motel, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a spa. On July 16, 2019, and August 5, 2019, the spa 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 handrail was not tight and secure; a gate did not self-close and latch; the chlorine and pH levels were not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; and, the spa temperature was not monitored by the facility.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars (**\$680.00**). The civil penalty has been paid.

16) Order Type and Number: Consent Order 19-276-RW  
Order Date: December 2, 2019  
Individual/Entity: **Andaman Limited, Inc.**  
Facility: Rodeway Inn  
Location: 1725 Kings Highway North  
Surfside Beach, SC 29575  
Mailing Address: Same  
County: Horry  
Previous Orders: None  
Permit/ID Number: 26-1862B  
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Andaman Limited, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On July 3, 2019, and August 8, 2019, 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 lifeline was not attached to the pool wall; the deck was uneven with sharp edges; the chlorine and pH levels were not within the acceptable range of water quality standards; the life ring was deteriorated; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars (**\$680.00**).



17) Order Type and Number: Consent Order 19-277-RW  
Order Date: December 3, 2019  
Individual/Entity: **Homeowners of Ocean Walk Property Owners Association**  
Facility: Ocean Walk  
Location: 9<sup>th</sup> South Ocean Boulevard  
North Myrtle Beach, SC 29582  
Mailing Address: Same  
County: Horry  
Previous Orders: None  
Permit/ID Number: 26-F02-1  
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Homeowners of Ocean Walk Property Owners Association (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On May 22, 2019, June 20, 2019, and August 13, 2019, 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 annual operating fee had not been paid; 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 life ring was missing.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of two thousand, forty dollars (**\$2,040.00**). The civil penalty has been paid.

18) Order Type and Number: Consent Order 19-278-RW  
Order Date: December 3, 2019  
Individual/Entity: **Aynor Area Recreational Corp., Inc.**  
Facility: Aynor Recreational Center  
Location: 1230 Bud Graham Road  
Aynor, SC 29511  
Mailing Address: Same  
County: Horry  
Previous Orders: None  
Permit/ID Number: 26-018-2  
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Aynor Area Recreational Corp., Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a kiddie pool. On June 18, 2019, and July 23, 2019, the kiddie 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; and, the chlorine and pH levels were not within the acceptable range of water quality standards.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars (**\$680.00**). The civil penalty has been paid.

- 19) Order Type and Number: Consent Order 19-279-RW  
Order Date: December 4, 2019  
Individual/Entity: **Noble Hotels, Inc.**  
Facility: Quality Inn St. George I-95  
Location: 6014 W. Jim Bilton Boulevard  
St. George, SC 29477  
Mailing Address: Same  
County: Dorchester  
Previous Orders: None  
Permit/ID Number: 18-025-1  
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Noble Hotels, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On June 21, 2019, and July 25, 2019, 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 lifeline floats were not properly spaced; the foot rinse shower was not operating properly; the bound and numbered log book was not maintained on a daily basis; a light in the pool wall was out of its niche; a gate did not self-close and latch; and, only one “Shallow Water – No Diving Allowed” sign was posted.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars (**\$680.00**). The civil penalty has been paid.

- 20) Order Type and Number: Consent Order 19-280-RW  
Order Date: December 5, 2019  
Individual/Entity: **Sandcreek Hills Property Owner**  
Facility: Sand Creek Hills  
Location: 101 Woodbury Drive  
Winnsboro, SC 29180  
Mailing Address: 215 Sandcreek Drive  
Winnsboro, SC 29180  
County: Fairfield  
Previous Orders: None  
Permit/ID Number: 20-010-1  
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Sandcreek Hills Property Owner (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On August 22, 2018, 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 closed to the public for a period in excess of twenty-four consecutive months and has not been filled in or removed. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: failure

to fill in or remove a pool, which has been closed for a period in excess of twenty-four consecutive months.

Action: The Individual/Entity is required to: submit to the Department for review and approval, a letter of intent to permanently close the pool by properly filling in or removing the pool; properly fill in or remove the pool in accordance with all of the conditions as stated in the Department's written notification of approval; contact Department staff to schedule an inspection to verify the completed work; and, pay a **stipulated penalty** in the amount of three hundred forty dollars (**\$340.00**) should any requirement of the Order not be met.

21) Order Type and Number: Consent Order 19-281-RW  
Order Date: December 9, 2019  
Individual/Entity: **Rosebank Condominium Horizontal Property Association**  
Facility: Rosebank Condos  
Location: 324 Laurens Street  
Aiken, SC 29801  
Mailing Address: Same  
County: Aiken  
Previous Orders: 17-080-RW (\$340.00)  
Permit/ID Number: 02-031-1  
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Rosebank Condominium Horizontal Property Association (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On July 3, 2019, and July 23, 2019, 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 lifeline floats were not properly spaced; a handrail and ladder were not tight and secure; the plaster on the pool floor was delaminated and had sharp edges; the pool rules sign was obstructed; the "No Lifeguard On Duty – Swim At Your Own Risk" signs were cracked; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of one thousand, three hundred sixty dollars (**\$1,360.00**).

22) Order Type and Number: Consent Order 19-282-RW  
Order Date: December 11, 2019  
Individual/Entity: **2000 Watermark Association, Inc.**  
Facility: 2000 Watermark  
Location: 2016 Watermark Place  
Columbia, SC 29210  
Mailing Address: 2000 Watermark Place

Columbia, SC 29210  
County: Richland  
Previous Orders: None  
Permit/ID Number: 40-09-1  
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: 2000 Watermark Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On July 2, 2019, July 18, 2019, and August 9, 2019, 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 handrail was not tight and secure; the plaster on the pool floor was delaminated; the pool floor was not clean; there was algae on the walls and floor of the pool; the water level was too low; the pump room was not accessible; the gate did not self-close and latch; the chlorine and pH levels were 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 bound and numbered log book was not available for review.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of two thousand, forty dollars (**\$2,040.00**).

23) Order Type and Number: Consent Order 19-284-RW  
Order Date: December 12, 2019  
Individual/Entity: **Fulton-Canterbury, LLC**  
Facility: Canterbury Apartments  
Location: 4636 Canterbury Drive  
Myrtle Beach, SC 29579  
Mailing Address: Same  
County: Horry  
Previous Orders: None  
Permit/ID Number: 26-M83-1  
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Fulton-Canterbury, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On June 5, 2019, and July 31, 2019, 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 debris in the skimmer baskets; a gate did not self-close and latch; the shepherd's crook was missing a bolt; only one "Shallow Water – No Diving Allowed" sign was posted; there were no "No Lifeguard On Duty – Swim At Your Own Risk" signs posted; and, the bound and numbered log book was not available for review on the first inspection and was not maintained on a daily basis on the second inspection.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars (**\$680.00**).

24) Order Type and Number: Consent Order 19-285-RW  
Order Date: December 16, 2019  
Individual/Entity: **WMJ, LLC**  
Facility: Sea Dip Resort  
Location: 2608 Ocean Boulevard  
Myrtle Beach, SC 29577  
Mailing Address: Same  
County: Horry  
Previous Orders: 17-092-RW (\$2,040.00);  
18-132-RW (\$2,240.00)  
Permit/ID Number: 26-Q21-1  
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: WMJ, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a spa. On June 14, 2019, and August 5, 2019, the spa 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.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of two thousand, seven hundred twenty dollars (**\$2,720.00**). The civil penalty has been paid.

25) Order Type and Number: Consent Order 19-286-RW  
Order Date: December 16, 2019  
Individual/Entity: **Ocean Crest Inn and Suites, LLC**  
Facility: Econo Lodge Inn & Suites  
Location: 601 South Ocean Boulevard  
Myrtle Beach, SC 29577  
Mailing Address: Same  
County: Horry  
Previous Orders: None  
Permit/ID Number: 26-263-1 & 26-G26-1  
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Ocean Crest Inn and Suites, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool and a spa. On June 28, 2019, and August 5, 2019, the pool and spa were inspected, and violations were 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 handrail was not tight and secure; a ladder was missing a bumper; the plaster on the pool floor was chipped; the chlorine and pH levels were not within the acceptable range of water quality standards; the bound and numbered log book was not maintained on a daily basis; the spa rules sign was damaged; the lifeline floats were not properly spaced; the water level was too low; the life ring was not properly hung in its designated location; the shepherd's crook

was not properly mounted in its designated location; and, a hose was being used to fill the spa.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of one thousand, three hundred sixty dollars (**\$1,360.00**).

26) Order Type and Number: Consent Order 19-287-RW  
Order Date: December 18, 2019  
Individual/Entity: **Yogeshwar, LLC**  
Facility: Country Inn & Suites  
Location: 2491Broad Street  
Sumter, SC 29150  
Mailing Address: Same  
County: Sumter  
Previous Orders: None  
Permit/ID Number: 43-1011B  
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Yogeshwar, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On August 8, 2019, and November 7, 2019, 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 main drain grates were not in place; the life ring rope was tangled; the current pool operator of record information was not posted to the public on the first inspection; the pool operator of record information posted was expired on the second inspection; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars (**\$680.00**).

27) Order Type and Number: Consent Order 19-288-RW  
Order Date: December 19, 2019  
Individual/Entity: **Paddlers Cove Property Owners Association, Inc.**  
Facility: Paddlers Cove  
Location: 2054 Paddlers Cove Drive  
Clover, SC 29710  
Mailing Address: Same  
County: York  
Previous Orders: None  
Permit/ID Number: 46-1190G  
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Paddlers Cove Property Owners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On May 30, 2019, and June 25, 2019, 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 gate did not self-close and latch; the chlorine level was not within the acceptable range of water quality standards; the pool rules sign did not have all of the required rules; only one “Shallow Water – No Diving Allowed” sign was posted on the first inspection; only one “No Lifeguard On Duty - Swim At Your Own Risk” sign was posted on the second inspection; both of the “No Lifeguard On Duty – Swim At Your Own Risk” signs were not visible on the second inspection; the current pool operator of record information was not posted to the public; there was debris in the skimmer baskets and the baskets were floating; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars (**\$680.00**). The civil penalty has been paid.

28) <u>Order Type and Number:</u>	Consent Order 19-289-RW
<u>Order Date:</u>	December 23, 2019
<u>Individual/Entity:</u>	<b>J &amp; P of Socastee, LLC</b>
<u>Facility:</u>	Super 8 by Wyndham Myrtle Beach/Market Common Area
<u>Location:</u>	3450 Hwy 17 Bypass S Myrtle Beach, SC 29577
<u>Mailing Address:</u>	Same
<u>County:</u>	Horry
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	26-E94-1
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-51(J)

Summary: J & P of Socastee, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On June 12, 2019, and July 30, 2019, 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 not tight and secure; the pH level was not within the acceptable range of water quality standards; a water hose was on the deck creating a trip hazard; the main drain grate was not in place; the life ring rope was too short; and, the pool rules sign was not completely filled out.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars (**\$680.00**). The civil penalty has been paid.

### Drinking Water Enforcement

29) Order Type and Number: Consent Order 19-025-DW  
Order Date: December 17, 2019  
Individual/Entity: **OneLife Institute, Inc.**  
Facility: Greenville Outdoor Center  
Location: 162 Sakanaga Trace  
Marietta, SC 29661  
Mailing Address: Same  
County: Greenville  
Previous Orders: None  
Permit/ID Number: 2370681  
Violations Cited: S.C. Code Ann. Regs. 61-58.17.K(1)

Summary: OneLife Institute, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS). On November 12, 2019, a violation was issued as a result of review of monitoring records. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: the PWS tested present for total coliform and E. coli, which resulted in a violation of the maximum contaminant level (MCL) for E. coli.

Action: The Individual/Entity is required to: 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.

### Water Pollution Enforcement

30) Order Type and Number: Consent Order 19-073-W  
Order Date: December 5, 2019  
Individual/Entity: **James C. Nichols, Sr.**  
Facility: Estates at Northampton Construction Site  
Location: Estates at Northampton, Lake Keowee  
Oconee County, SC  
Mailing Address: 102 Greenleaf Lane  
Easley, SC 29642  
County: Oconee  
Previous Orders: None  
Permit/ID Number: SCR10Y218  
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-90(A) (Supp. 2018); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a) and (e) (2011).



Summary: James C. Nichols, Sr. (Individual/Entity) is responsible for land disturbing activity on property located in Oconee County, South Carolina. On August 6, 2019, a Notice of Violation was issued as a result of failure to maintain sediment and erosion controls and unauthorized discharges of sediment associated with construction. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permit Regulations, as follows: discharged sediment into the environment, including waters of the state, in a manner other than in compliance with a permit issued by the Department and failed to install and maintain storm water, sediment, and erosion control measures in accordance with the approved storm water pollution prevention plan (SWPPP).

Action: The Individual/Entity is required to: submit a revised SWPPP; submit an engineer's report confirming the site is in compliance with the approved SWPPP; submit a Notice of Termination upon stabilization of the site; and pay a civil penalty in the amount of eight thousand, four hundred dollars (**\$8,400.00**).

31) Order Type and Number: Consent Order 19-074-W  
Order Date: December 10, 2019  
Individual/Entity: **Town of Winnsboro**  
Facility: Town of Winnsboro WWTF  
Location: near HWY 321 Bypass, Winnsboro  
Fairfield County, SC  
Mailing Address: P.O. Box 209  
Winnsboro, SC 29180  
County: Fairfield  
Previous Orders: None  
Permit/ID Number: NPDES Permit SC0020215  
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d) (2008 & Supp. 2018); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a) and (d) (2011).

Summary: The Town of Winnsboro (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Fairfield County, South Carolina. On June 21, 2019, a Notice of Violation was issued as a result of violations of Escherichia coli (E. coli) reported on discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permit Regulations in that it failed to comply with the effluent discharge limits of the National Pollutant Discharge Elimination System Permit for E. coli.

Action: The Individual/Entity is required to: submit a Corrective Action Plan (CAP) addressing the deficiencies and pay a civil penalty in the amount of three thousand, four hundred dollars (**\$3,400.00**).

32) Order Type and Number: Consent Order 19-075-W  
Order Date: December 11, 2019  
Individual/Entity: **Celanese LTD**  
Facility: Celanese LTD WWTF  
Location: 14355 Highway 221  
Enoree, SC 29335  
Mailing Address: Same  
County: Spartanburg  
Previous Orders: None  
Permit/ID Number: NPDES Permit SC0038229  
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d) (2008 & Supp. 2018), and Water Pollution Control Permits Regulation, S.C. Code Ann. Regs. 61-9.122.41(a) (2011), and NPDES Permit SC0028229

Summary: Celanese LTD (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Spartanburg County, South Carolina. On August 27, 2019, a Notice of Violation was issued as a result of phosphorus violations reported on discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulation, as follows: failed to comply with the permitted effluent limitations for total phosphorus specified within its National Pollutant Discharge Elimination System permit.

Action: The Individual/Entity is required to: submit a CAP addressing the deficiencies; and, pay a civil penalty in the amount of two thousand, one hundred dollars (**\$2,100.00**).

33) Order Type and Number: Consent Order 19-076-W  
Order Date: December 17, 2019  
Individual/Entity: **City of Barnwell**  
Facility: City of Barnwell WWTF  
Location: 399 Seay Street  
Barnwell, SC 29812  
Mailing Address: P.O. Box 776  
Barnwell, SC 29812  
County: Barnwell  
Previous Orders: None  
Permit/ID Number: NPDES Permit SC0047872  
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d) (2008 & Supp. 2018); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a) (2011).

Summary: The City of Barnwell (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Barnwell County, South Carolina. On August 22, 2019, a Notice of Violation was issued

as a result of dissolved oxygen (DO) violations reported on discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permit Regulations, as follows: failed to comply with the effluent discharge limits of the National Pollutant Discharge Elimination System Permit for DO.

Action: The Individual/Entity is required to: submit to the Department a Corrective Action Plan (CAP) addressing the deficiencies; and, pay a civil penalty in the amount of two thousand, eight hundred dollars (**\$2,800.00**).

34) Order Type and Number: Consent Order 19-077-W  
Order Date: December 17, 2019  
Individual/Entity: **Harold Brock**  
Facility: Site 1 and Site 2  
Location: TMS#2370006002(Site1),  
TMS#2370009009, TMS#2370009002,  
TMS#2370009001 (Site 2)  
Mailing Address: 2522 River Road  
Piedmont, SC 29673  
County: Anderson  
Previous Orders: None  
Permit/ID Number: N/A  
Violations Cited: Pollution Control Act, S.C Code Ann. § 48-1-90 (A) and § 48-1- 110 (d) (2008 & Supp. 2018); Water Pollution Control Permits, S.C. Code Ann. Regs. 61-9.122.26 (a) (2011).

Summary: Harold Brock (Individual/Entity) owns and is responsible for land disturbing activity located in Anderson County, South Carolina. On May 22, 2019, a Notice of Violation was issued as a result of failure to obtain permit coverage prior to initiating land disturbing activities. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permit Regulations, as follows: failed to acquire permit coverage and allowed sediment to leave to site in a manner other than in compliance with a permit issued by the Department.

Action: The Individual/Entity is required to: submit a Storm Water Pollution Prevention Plan (SWPPP), submit a administratively complete NPDES General Permit for Storm Water Discharges for Site 1 and Site 2, submit administratively complete Notice of Termination (NOT) after completion of permanent stabilization of the Sites, and pay a civil penalty in the amount of ten thousand dollars (**\$10,000.00**).

35) Order Type and Number: Consent Order 19-078-W  
Order Date: December 17, 2019  
Individual/Entity: **Granite Hermitage Farms, LLC**  
Facility: Hermitage Farms Mobile Home Park  
WWTF  
Location: 175 Precipice Road  
Camden, SC 29020  
Mailing Address: Same  
County: Kershaw  
Previous Orders: 17-001-W (\$2,100.00)  
Permit/ID Number: State Land Application Permit ND0067024  
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d) (2008 & Supp. 2018); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.505.41 (a) (2011).

Summary: Granite Hermitage Farms, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Kershaw County, South Carolina. On July 17, 2019, a Notice of Violation was issued as a result of a violations of biochemical oxygen demand (BOD) and total suspended solids (TSS) reported on the discharge monitoring report submitted to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permit Regulations, as follows: failed to comply with the effluent discharge limits of the National Pollutant Discharge Elimination System Permit for BOD and TSS.

Action: The Individual/Entity is required to: submit a Corrective Action Plan (CAP) addressing the deficiencies and pay a civil penalty in the amount of eight thousand, four hundred dollars (**\$8,400.00**).

36) Order Type and Number: Consent Order 19-079-W  
Order Date: December 20, 2019  
Individual/Entity: **Town of Wagener**  
Facility: Town of Wagener WWTF  
Location: 151 Woodshore Drive  
Wagener, SC 29164  
Mailing Address: P.O. Box 400  
Wagener, SC 29164  
County: Aiken  
Previous Orders: None  
Permit/ID Number: NPDES Permit SC0026204  
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d) (2008 & Supp. 2018); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a) (2011).

Summary: The Town of Wagener (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Aiken County, South Carolina. On July 17, 2019, a Notice of Violation was issued as a result of violations of ammonia-nitrogen (Ammonia) being reported on discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permit Regulations, as follows: failed to comply with the effluent discharge limits of the National Pollutant Discharge Elimination System Permit for Ammonia.

Action: The Individual/Entity is required to: submit to the Department a Corrective Action Plan (CAP) addressing the deficiencies and pay a civil penalty in the amount of one thousand, four hundred dollars (**\$1,400.00**).

## **BUREAU OF ENVIRONMENTAL HEALTH SERVICES**

### **Food Safety Enforcement**

37) Order Type and Number: Consent Order 2019-206-01-052  
Order Date: December 2, 2019  
Individual/Entity: **Anderson Wings LLC**  
Facility: Anderson Wings LLC  
Location: 119 Interstate Boulevard  
Anderson, SC 29621  
Mailing Address: 830 Lowcountry Boulevard, Suite 200  
Mount Pleasant, SC 29624  
County: Anderson  
Previous Orders: 2018-206-01-006 (\$1,000.00);  
2019-206-01-012 (\$1,750.00)  
Permit Number: 04-206-04218  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Anderson Wings LLC (Individual/Entity) is a restaurant located in Anderson, South Carolina. The Department conducted inspections on June 25, 2019, and July 3, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that physical facilities were maintained in good repair.

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**).

38) Order Type and Number: Consent Order 2019-206-05-018  
Order Date: December 2, 2019  
Individual/Entity: **Santee Seafood Bistro-N-Fresh Market**  
Facility: Santee Seafood Bistro-N-Fresh Market  
Location: 648 Bass Drive  
Santee, SC 29142  
Mailing Address: P.O. Box 1202  
Santee, SC 29142  
County: Orangeburg  
Previous Orders: None  
Permit Number: 38-206-02688  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Santee Seafood Bistro-N-Fresh Market (Individual/Entity) is a restaurant located in Santee, South Carolina. The Department conducted inspections on August 16, 2018, August 23, 2018, and July 11, 2019. 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**).

39) Order Type and Number: Consent Order 2019-206-05-022  
Order Date: December 2, 2019  
Individual/Entity: **Little Caesars**  
Facility: Little Caesars  
Location: 165 Market Place Drive  
North Augusta, SC 29841  
Mailing Address: 803 Dover Court  
Grovetown, GA 30813  
County: Aiken  
Previous Orders: None  
Permit Number: 02-206-02874  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Little Caesars (Individual/Entity) is a restaurant located in North Augusta, South Carolina. The Department conducted inspections on July 30, 2019, August 8, 2019, August 15, 2019, and August 22, 2019. 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, six hundred dollars (**\$1,600.00**).

40) Order Type and Number: Consent Order 2019-206-05-029  
Order Date: December 2, 2019  
Individual/Entity: **Subway**  
Facility: Subway  
Location: 1255 John C. Calhoun Drive  
Orangeburg, SC 20115  
Mailing Address: Same  
County: Orangeburg  
Previous Orders: None  
Permit Number: 38-206-02162  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Subway (Individual/Entity) is a restaurant located in Orangeburg, South Carolina. The Department conducted inspections on February 13, 2019, October 14, 2019, and October 23, 2019. 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**).

41) Order Type and Number: Consent Order 2019-206-06-100  
Order Date: December 2, 2019  
Individual/Entity: **Scotchman #3226**  
Facility: Scotchman #3226  
Location: 300 Hilton Road  
Myrtle Beach, SC 29572  
Mailing Address: P. O. Box 3227  
Wilmington, NC 28406  
County: Horry  
Previous Orders: None  
Permit Number: 26-206-12494  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Scotchman #3226 (Individual/Entity) is a convenience store located in Myrtle Beach, South Carolina. The Department conducted inspections on June 11, 2018, June 22, 2018, June 10, 2019, June 20, 2019, and June 28, 2019. 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, one hundred fifty dollars (**\$2,150.00**).

42) Order Type and Number: Consent Order 2019-206-06-137  
Order Date: December 2, 2019  
Individual/Entity: **Theo's Pancake House**  
Facility: Theo's Pancake House  
Location: 9924 North Kings Highway  
Myrtle Beach, SC 29572  
Mailing Address: Same  
County: Horry  
Previous Orders: None  
Permit Number: 26-206-13680  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Theo's Pancake House (Individual/Entity) is a restaurant located in Myrtle Beach, South Carolina. The Department conducted inspections on June 18, 2019, June 28, 2019, and August 19, 2019. 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**).

43) Order Type and Number: Consent Order 2019-206-06-138  
Order Date: December 2, 2019  
Individual/Entity: **Bond Fire DBA Art Burger Sushi**  
Facility: Bond Fire DBA Art Burger Sushi  
Location: 706 A North Ocean Boulevard  
Myrtle Beach, SC 29577  
Mailing Address: 1408 Thomas Circle  
Myrtle Beach, SC 29577  
County: Horry  
Previous Orders: None  
Permit Number: 26-206-12745  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Bond Fire DBA Art Burger Sushi (Individual/Entity) is a restaurant located in Myrtle Beach, South Carolina. The Department conducted inspections on March 5, 2019, June 26, 2019, August 27, 2019, and August 30, 2019. 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 one thousand, six hundred dollars (**\$1,600.00**).



44) Order Type and Number: Consent Order 2019-206-06-146  
Order Date: December 2, 2019  
Individual/Entity: **Molly Darcy's**  
Facility: Molly Darcy's  
Location: 1701 South Ocean Boulevard  
North Myrtle Beach, SC 29582  
Mailing Address: Same  
County: Horry  
Previous Orders: None  
Permit Number: 26-206-09771  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Molly Darcy's (Individual/Entity) is a restaurant located in North Myrtle Beach, South Carolina. The Department conducted inspections on October 15, 2018, March 19, 2019, and October 3, 2019. 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**).

45) Order Type and Number: Consent Order 2019-206-07-077  
Order Date: December 2, 2019  
Individual/Entity: **Groucho's Deli of Charleston**  
Facility: Groucho's Deli of Charleston  
Location: 364 King Street, Suite A  
Charleston, SC 29401  
Mailing Address: Same  
County: Charleston  
Previous Orders: None  
Permit Number: 10-206-04083  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Groucho's Deli of Charleston (Individual/Entity) is a restaurant located in Charleston, South Carolina. The Department conducted inspections on August 29, 2017, June 19, 2018, and June 19, 2019. 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**).

46) Order Type and Number: Consent Order 2019-206-07-095  
Order Date: December 2, 2019  
Individual/Entity: **Brown's Court Baker**  
Facility: Brown's Court Baker  
Location: 199 St. Philip Street  
Charleston, SC 29403  
Mailing Address: Same  
County: Charleston  
Previous Orders: None  
Permit Number: 10-206-08516  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Brown's Court Baker (Individual/Entity) is a restaurant located in Charleston, South Carolina. The Department conducted inspections on October 31, 2017, November 8, 2017, August 16, 2018, August 22, 2018, August 7, 2019, and August 15, 2019. 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 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 two thousand dollars (**\$2,000.00**).

47) Order Type and Number: Consent Order 2019-206-07-097  
Order Date: December 2, 2019  
Individual/Entity: **Perkins #2574**  
Facility: Perkins #2574  
Location: 1700 Old Trolley Road  
Summerville, SC 29485  
Mailing Address: P.O. Box 1677  
Summerville, SC 29485  
County: Dorchester  
Previous Orders: None  
Permit Number: 18-206-04640  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Perkins #2574 (Individual/Entity) is a restaurant located in Summerville, South Carolina. The Department conducted inspections on August 15, 2018, August 16, 2018, August 12, 2019, and August 15, 2019. 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 provide equipment sufficient in number and capacity to maintain food temperatures for cooling and heating food and holding cold and hot 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, six hundred dollars (**\$1,600.00**).

48) Order Type and Number: Consent Order 2019-206-07-104  
Order Date: December 2, 2019  
Individual/Entity: **Hardee's #1070**  
Facility: Hardee's #1070  
Location: 209 Spring Street  
Charleston, SC 29403  
Mailing Address: 5305 Spine Road, Suite A  
Boulder, CO 80301  
County: Charleston  
Previous Orders: 2019-206-07-034 (\$800.00)  
Permit Number: 10-206-09421  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Hardee's #1070 (Individual/Entity) is a restaurant located in Charleston, South Carolina. The Department conducted inspections on April 4, 2019, August 19, 2019, and August 20, 2019. 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; failed to ensure that outer openings of the retail food establishment were protected against the entry of insects and rodents by filling or closing the holes and other gaps along floors, walls and ceiling; closed tight-fitting windows; and solid, self-closing doors; failed to ensure that equipment is maintained in a state of repair and condition that meets the regulation requirements; failed to ensure that physical facilities were maintained in good repair; and failed to clean the physical facilities as often as necessary to keep them clean.

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, five hundred dollars (**\$2,500.00**).

49) Order Type and Number: Consent Order 2019-206-07-117  
Order Date: December 2, 2019  
Individual/Entity: **Arby's #1114**  
Facility: Arby's #1114  
Location: 1646 Sam Rittenberg Boulevard  
Charleston, SC 29407  
Mailing Address: 1155 Perimeter Center West, 5<sup>th</sup> Floor  
Atlanta, GA 30338  
County: Charleston  
Previous Orders: None  
Permit Number: 10-206-00149

Violations Cited:

S.C. Code Ann. Regs. 61-25

Summary: Arby's #1114 (Individual/Entity) is a restaurant located in Charleston, South Carolina. The Department conducted inspections on May 29, 2018, May 2, 2019, August 26, 2019, and August 30, 2019. 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 provide equipment sufficient in number and capacity to maintain food temperatures for cooling and heating food and holding cold and hot 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, six hundred dollars (**\$1,600.00**).

50) Order Type and Number: Consent Order 2019-206-01-057  
Order Date: December 3, 2019  
Individual/Entity: **Huddle House #111**  
Facility: Huddle House #111  
Location: 5420 Highway 187  
Anderson, SC 29625  
Mailing Address: 5901-B Peachtree Dunwoody NE, Suite 450  
Atlanta, GA 30328  
County: Anderson  
Previous Orders: 2019-206-01-051 (\$400.00)  
Permit Number: 04-206-04413  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Huddle House #111 (Individual/Entity) is a restaurant located in Anderson, South Carolina. The Department conducted inspections on February 11, 2019, June 27, 2019, August 8, 2019, August 9, 2019, and August 16, 2019. 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 ensure that outer openings of the retail food establishment were protected against the entry of insects and rodents by filling or closing the holes and other gaps along floors, walls and ceiling; closed tight-fitting windows; and solid, self-closing doors; failed to ensure that equipment is maintained in a state of repair and condition that meets the regulation requirements; failed to keep food contact surfaces of cooking equipment and pans free of encrusted grease deposits and other soil accumulations and non-food contact surfaces clean and free of accumulation of dust, dirt, food residue, and other debris; and failed to clean the physical facilities as often as necessary to keep them clean.

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, seven hundred fifty dollars (**\$2,750.00**).

51) Order Type and Number: Consent Order 2019-206-02-084  
Order Date: December 3, 2019  
Individual/Entity: **Sticky Fingers**  
Facility: Sticky Fingers  
Location: 1 South Main Street  
Greenville, SC 29601  
Mailing Address: Same  
County: Greenville  
Previous Orders: None  
Permit Number: 23-206-10447  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Sticky Fingers (Individual/Entity) is a restaurant located in Greenville, South Carolina. The Department conducted inspections on January 3, 2019, April 4, 2019, and September 24, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

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**).

52) Order Type and Number: Consent Order 2019-206-02-088  
Order Date: December 3, 2019  
Individual/Entity: **Waffle House #1524**  
Facility: Waffle House #1524  
Location: 1064 Tiger Boulevard  
Clemson, SC 29631  
Mailing Address: P.O. Box 6450  
Norcross, GA 30091  
County: Pickens  
Previous Orders: None  
Permit Number: 39-206-01184  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Waffle House #1524 (Individual/Entity) is a restaurant located in Clemson, South Carolina. The Department conducted inspections on March 13, 2018, March 22, 2018, January 24, 2019, and October 29, 2019. 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, six hundred dollars (**\$1,600.00**).

53) Order Type and Number: Consent Order 2019-206-03-097  
Order Date: December 3, 2019  
Individual/Entity: **Pitt Stop #47/Blimpie #77**  
Facility: Pitt Stop #47/Blimpie #77  
Location: 3809 Sunset Boulevard  
West Columbia, SC 29169  
Mailing Address: 279 Cedarcrest Drive  
Lexington, SC 29072  
County: Lexington  
Previous Orders: None  
Permit Number: 32-206-06732  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Pitt Stop #47/Blimpie #77 (Individual/Entity) is a convenience store/restaurant located in West Columbia, South Carolina. The Department conducted inspections on August 14, 2018, August 6, 2019, August 16, 2019, August 26, 2019, September 5, 2019, September 13, 2019, September 23, 2019, and October 10, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that a person in charge is certified by a food protection manager certification program that is recognized by the Conference for Food Protection.

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, obtain and provide documentation of its designated employee's completion of the certified food protection manager certification program; and pay a civil penalty in the amount of one thousand, two hundred dollars (**\$1,200.00**).

54) Order Type and Number: Consent Order 2019-206-04-052  
Order Date: December 3, 2019  
Individual/Entity: **Hampton Inn & Suites**  
Facility: Hampton Inn & Suites  
Location: 203 East Carolina Avenue  
Hartsville, SC 29550  
Mailing Address: Same  
County: Darlington  
Previous Orders: None  
Permit Number: 16-206-03148  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Hampton Inn & Suites (Individual/Entity) operates a restaurant located in Hartsville, South Carolina. The Department conducted inspections on August 15, 2017, August 7, 2018, and August 5, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that refrigerated, ready-

to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

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**).

55) Order Type and Number: Consent Order 2019-206-04-062  
Order Date: December 3, 2019  
Individual/Entity: **Alco #23**  
Facility: Alco #23  
Location: 711 East Market Street  
Cheraw, SC 29520  
Mailing Address: P.O. Box 1059  
Albemarle, NC 28001  
County: Chesterfield  
Previous Orders: None  
Permit Number: 13-206-01301  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Alco #23 (Individual/Entity) is a convenience store/restaurant located in Cheraw, South Carolina. The Department conducted inspections on March 3, 2017, February 21, 2018, February 28, 2018, January 18, 2019, January 28, 2019, February 7, 2019, July 2, 2019, July 12, 2019, July 22, 2019, and August 1, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that a person in charge is certified by a food protection manager certification program that is recognized by the Conference for Food Protection.

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, obtain and provide documentation of its designated employee's completion of the certified food protection manager certification program; and pay a civil penalty in the amount of one thousand, six hundred dollars (**\$1,600.00**).

56) Order Type and Number: Consent Order 2019-206-05-028  
Order Date: December 3, 2019  
Individual/Entity: **Huddle House #3117**  
Facility: Huddle House #3117  
Location: 651 Bettis Academy Road  
Graniteville, SC 29829  
Mailing Address: 2440 Whitehall Park Drive, Suite 800  
Charlotte, NC 28273  
County: Aiken  
Previous Orders: None

Permit Number: 02-206-02911  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Huddle House #3117 (Individual/Entity) is a restaurant located in Graniteville, South Carolina. The Department conducted inspections on August 6, 2019, August 13, 2019, and October 9, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that when time without temperature control is used as a public health control, foods with expired time labels, unmarked containers or packages, were 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**).

57) Order Type and Number: Consent Order 2019-206-07-112  
Order Date: December 3, 2019  
Individual/Entity: **Mozzo Deli Caterer**  
Facility: Mozzo Deli Caterer  
Location: 730 Coleman Boulevard  
Mount Pleasant, SC 29464  
Mailing Address: Same  
County: Charleston  
Previous Orders: 2019-206-07-020 (\$800.00)  
Permit Number: 10-206-07060  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Mozzo Deli Caterer (Individual/Entity) is a restaurant located in Mount Pleasant, South Carolina. The Department conducted inspections on February 27, 2019, September 11, 2019, and September 19, 2019. 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; 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 dollars (**\$1,000.00**).

58) Order Type and Number: Consent Order 2019-211-07-004  
Order Date: December 3, 2019  
Individual/Entity: **Chihuahua Super Market**  
Facility: Chihuahua Super Market  
Location: 3387 Ashley Phosphate Road  
North Charleston, SC 29418  
Mailing Address: Same



County: Charleston  
Previous Orders: 2016-211-07-001 (\$1,200.00);  
2018-211-07-001 (\$800.00);  
2019-211-07-002 (\$1,000.00)  
Permit Number: 10-211-09349  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Chihuahua Super Market (Individual/Entity) is a retail food store located in North Charleston, South Carolina. The Department conducted inspections on July 18, 2017, July 28, 2017, May 30, 2018, June 8, 2018, February 28, 2019, March 7, 2019, April 23, 2019, June 27, 2019, and July 8, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that a person in charge is certified by a food protection manager certification program that is recognized by the Conference for Food Protection.

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, obtain and provide documentation of its designated employee's completion of the certified food protection manager certification program, and pay a civil penalty in the amount of one thousand, seven hundred fifty dollars (**\$1,750.00**).

59) Order Type and Number: Consent Order 2019-206-06-149  
Order Date: December 5, 2019  
Individual/Entity: **Valentino Italian Restaurant**  
Facility: Valentino Italian Restaurant  
Location: 323 Highway 17 North  
Surfside Beach, SC 29575  
Mailing Address: Same  
County: Horry  
Previous Orders: 2016-206-04-006 (\$800.00);  
2017-206-06-052 (\$400.00);  
2018-206-06-071 (\$1,000.00)  
Permit Number: 26-206-11890  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Valentino Italian Restaurant (Individual/Entity) is a restaurant located in Surfside Beach, South Carolina. The Department conducted inspections on March 19, 2019, April 12, 2019, and September 18, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

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**).

60) Order Type and Number: Consent Order 2019-206-08-010  
Order Date: December 5, 2019  
Individual/Entity: **Peking House**  
Facility: Peking House  
Location: 2317 Boundary Street  
Beaufort, SC 29902  
Mailing Address: Same  
County: Beaufort  
Previous Orders: None  
Permit Number: 07-206-02775  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Peking House (Individual/Entity) operates a restaurant located in Beaufort, South Carolina. The Department conducted inspections on February 5, 2019, September 25, 2019, and October 4, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure employees wash hands after engaging in activities that contaminate their hands.

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**).

61) Order Type and Number: Consent Order 2019-206-04-048  
Order Date: December 6, 2019  
Individual/Entity: **Effingham Grocery and Grill**  
Facility: Effingham Grocery and Grill  
Location: 710 East Effingham Road  
Effingham, SC 29541  
Mailing Address: 2502 Olanta Highway  
Effingham, SC 29541  
County: Florence  
Previous Orders: None  
Permit Number: 21-206-02683  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Effingham Grocery and Grill (Individual/Entity) is a convenience store/restaurant located in Effingham, South Carolina. The Department conducted inspections on March 27, 2018, March 5, 2019, March 15, 2019, and June 26, 2019. 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, six hundred dollars (**\$1,600.00**).

62) Order Type and Number: Consent Order 2019-206-04-058  
Order Date: December 6, 2019  
Individual/Entity: **Tommy's**  
Facility: Tommy's  
Location: 960 Lydia Highway  
Hartsville, SC 29550  
Mailing Address: 3316 Cherrywood Road  
Florence, SC 29501  
County: Darlington  
Previous Orders: 2015-206-03-111 (\$800.00)  
Permit Number: 16-206-02045  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Tommy's (Individual/Entity) is a restaurant located in Hartsville, South Carolina. The Department conducted inspections on October 17, 2017, October 17, 2018, and August 12, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

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**).

63) Order Type and Number: Consent Order 2019-206-04-064  
Order Date: December 6, 2019  
Individual/Entity: **Little Caesar's Pizza #17595**  
Facility: Little Caesar's Pizza #17595  
Location: 2077 Wedgefield Road  
Sumter, SC 29150  
Mailing Address: Same  
County: Sumter  
Previous Orders: None  
Permit Number: 43-206-01077  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Little Caesar's Pizza #17595 (Individual/Entity) is a restaurant located in Sumter, South Carolina. The Department conducted inspections on October 8, 2019, October 17, 2019, and October 25, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to keep equipment food contact surfaces and utensils clean to sight and touch.

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**).

64) Order Type and Number: Consent Order 2019-206-04-067  
Order Date: December 6, 2019  
Individual/Entity: **Hong Kong Chinese Restaurant**  
Facility: Hong Kong Chinese Restaurant  
Location: 821 West Carolina Avenue  
Hartsville, SC 29550  
Mailing Address: Same  
County: Darlington  
Previous Orders: None  
Permit Number: 16-206-01685  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Hong Kong Chinese Restaurant (Individual/Entity) is a restaurant located in Hartsville, South Carolina. The Department conducted inspections on April 3, 2018, August 31, 2018, and August 27, 2019. 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 refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

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 2019-206-06-107  
Order Date: December 6, 2019  
Individual/Entity: **Scott's BBQ**  
Facility: Scott's BBQ  
Location: 2734 Hemingway Highway  
Hemingway, SC 29554  
Mailing Address: Same  
County: Williamsburg  
Previous Orders: 2017-206-06-139 (\$1,200.00)

Permit Number: 45-206-00442  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Scott's BBQ (Individual/Entity) is a restaurant located in Hemingway, South Carolina. The Department conducted inspections on May 30, 2018, November 2, 2018, and July 24, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to clean the physical facilities as often as necessary to keep them clean and failed to ensure the premises is free of litter and items that are unnecessary to the operation or maintenance of the establishment such as equipment that is nonfunctional or no longer used.

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 fifty dollars (**\$250.00**).

66) Order Type and Number: Consent Order 2019-206-06-142  
Order Date: December 6, 2019  
Individual/Entity: **China Buffet**  
Facility: China Buffet  
Location: 1105 Church Street  
Conway, SC 29526  
Mailing Address: Same  
County: Horry  
Previous Orders: None  
Permit Number: 26-206-11146  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: China Buffet (Individual/Entity) is a restaurant located in Conway, South Carolina. The Department conducted inspections on September 6, 2018, May 30, 2019, and September 20, 2019. 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 2019-206-06-150  
Order Date: December 6, 2019  
Individual/Entity: **Original Shuckers Raw Bar**  
Facility: Original Shuckers Raw Bar  
Location: 300 North Kings Highway  
Myrtle Beach, SC 29577  
Mailing Address: Same

County: Horry  
Previous Orders: 2017-206-06-116 (\$400.00);  
2018-206-06-054 (\$200.00)  
Permit Number: 26-206-07497  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Original Shuckers Raw Bar (Individual/Entity) is a restaurant located in Myrtle Beach, South Carolina. The Department conducted inspections on April 23, 2019, September 26, 2019, and October 2, 2019. 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**).

68) Order Type and Number: Consent Order 2019-206-07-108  
Order Date: December 6, 2019  
Individual/Entity: **Grand Bohemian Hotel**  
Facility: Grand Bohemian Hotel  
Location: 55 Wentworth Street  
Charleston, SC 29401  
Mailing Address: 4901 Vineland Road, Suite 650  
Orlando, FL 32811  
County: Charleston  
Previous Orders: None  
Permit Number: 10-206-09610  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Grand Bohemian Hotel (Individual/Entity) operates a restaurant located in Charleston, South Carolina. The Department conducted inspections on November 28, 2017, August 28, 2018, September 5, 2018, and August 26, 2019. 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**).

69) Order Type and Number: Consent Order 2019-206-08-011  
Order Date: December 6, 2019  
Individual/Entity: **Jim N Nick's Bar-B-Q**  
Facility: Jim N Nick's Bar-B-Q  
Location: 872 Fording Island Road

Mailing Address: Bluffton, SC 29910  
10 Iverness Center Parkway, Suite 250  
Birmingham, AL 35242  
County: Beaufort  
Previous Orders: 2017-206-08-008 (\$800.00)  
Permit Number: 07-206-06036  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Jim N Nick's Bar-B-Q (Individual/Entity) is a restaurant located in Bluffton, South Carolina. The Department conducted inspections on September 25, 2018, August 5, 2019, and October 9, 2019. 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**).

70) Order Type and Number: Consent Order 2019-206-01-070  
Order Date: December 12, 2019  
Individual/Entity: **Fatz**  
Facility: Fatz  
Location: 105 Interstate Boulevard  
Anderson, SC 29621  
Mailing Address: 4324 Wade Hampton Boulevard, Suite B  
Taylors, SC 29687  
County: Anderson  
Previous Orders: None  
Permit Number: 04-206-04540  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Fatz (Individual/Entity) is a restaurant located in Anderson, South Carolina. The Department conducted inspections on May 22, 2019, August 20, 2019, and August 30, 2019. 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**).

71) Order Type and Number: Consent Order 2019-206-03-085  
Order Date: December 10, 2019  
Individual/Entity: **El Paso**  
Facility: El Paso  
Location: 1937 Augusta Highway  
Lexington, SC 29072  
Mailing Address: 1317 Petsites Road  
Chapin, SC 29036  
County: Lexington  
Previous Orders: 2016-206-03-079 (\$800.00);  
2017-206-03-019 (\$4,000.00);  
2017-206-03-067 (\$2,250.00);  
2018-206-03-118 (\$4,250.00)  
Permit Number: 32-206-06469  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: El Paso (Individual/Entity) is a restaurant located in Lexington, South Carolina. The Department conducted inspections on August 24, 2017, July 18, 2018, and July 12, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

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**).

72) Order Type and Number: Consent Order 2019-206-04-065  
Order Date: December 10, 2019  
Individual/Entity: **Taco Bell #31789**  
Facility: Taco Bell #31789  
Location: 25 North Lafayette Drive  
Sumter, SC 29150  
Mailing Address: P.O. Box 507  
West Linn, OR 97068  
County: Sumter  
Previous Orders: None  
Permit Number: 43-206-01213  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Taco Bell #31789 (Individual/Entity) is a restaurant located in Sumter, South Carolina. The Department conducted inspections on September 20, 2019, September 27, 2019, and October 4, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that multiuse food-contact surfaces were smooth, free of breaks, open seams, cracks, chips, inclusions, pits, and



similar imperfections; free of sharp internal angles, corners, and crevices; finished to have smooth welds and joints; and accessible for cleaning; and failed to provide a test kit or other device that accurately measures the concentration of MG/L of sanitizing solutions.

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**).

73) Order Type and Number: Consent Order 2019-206-04-069  
Order Date: December 10, 2019  
Individual/Entity: **No. 1 Chinese Restaurant**  
Facility: No. 1 Chinese Restaurant  
Location: 1111 East Godbold Street  
Marion, SC 29571  
Mailing Address: Same  
County: Marion  
Previous Orders: 2015-206-04-023 (\$1,200.00)  
Permit Number: 33-206-00830  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: No. 1 Chinese Restaurant (Individual/Entity) is a restaurant located in Marion, South Carolina. The Department conducted inspections on February 14, 2018, August 20, 2018, and July 18, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

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**).

74) Order Type and Number: Consent Order 2019-206-06-148  
Order Date: December 10, 2019  
Individual/Entity: **McDonald's Surfside #38987**  
Facility: McDonald's Surfside #38987  
Location: 5900 South Kings Highway  
Myrtle Beach, SC 29575  
Mailing Address: 171 McDonald's Court  
Myrtle Beach, SC 29588  
County: Horry  
Previous Orders: None  
Permit Number: 26-206-13835  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: McDonald's Surfside #38987 (Individual/Entity) is a restaurant located in Myrtle Beach, South Carolina. The Department conducted inspections on March 21, 2019, April 8, 2019, and September 24, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to store poisonous or toxic materials so that they cannot contaminate food equipment, utensils, linens, and single-service and single-use articles.

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**).

75) Order Type and Number: Consent Order 2019-206-06-153  
Order Date: December 10, 2019  
Individual/Entity: **McDonald's #07648**  
Facility: McDonald's #07648  
Location: 4500 Highway 17 Bypass South  
Myrtle Beach, SC 29588  
Mailing Address: 171 McDonald's Court  
Myrtle Beach, SC 29588  
County: Horry  
Previous Orders: None  
Permit Number: 26-206-01135  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: McDonald's #07648 (Individual/Entity) is a restaurant located in Myrtle Beach, South Carolina. The Department conducted inspections on October 1, 2018, April 2, 2019, and October 10, 2019. 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 eight hundred dollars (**\$800.00**).

76) Order Type and Number: Consent Order 2019-206-07-123  
Order Date: December 10, 2019  
Individual/Entity: **Poogan's Porch**  
Facility: Poogan's Porch  
Location: 90 Queen Street  
Charleston, SC 29401  
Mailing Address: Same  
County: Charleston  
Previous Orders: None

Permit Number: 10-206-01692  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Poogan's Porch (Individual/Entity) is a restaurant located in Charleston, South Carolina. The Department conducted inspections on November 30, 2017, September 26, 2018, April 9, 2019, and October 29, 2019. 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 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 one thousand, six hundred dollars (**\$1,600.00**).

77) Order Type and Number: Consent Order 2019-206-04-066  
Order Date: December 12, 2019  
Individual/Entity: **China 1**  
Facility: China 1  
Location: 1240 Bennettsville Square  
Bennettsville, SC 29512  
Mailing Address: Same  
County: Marlboro  
Previous Orders: None  
Permit Number: 34-206-00630  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: China 1 (Individual/Entity) is a restaurant located in Bennettsville, South Carolina. The Department conducted inspections on May 22, 2018, August 6, 2018, January 29, 2019, and August 22, 2019. 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 ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

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, eight hundred dollars (**\$1,800.00**).

78) Order Type and Number: Consent Order 2019-206-01-077  
Order Date: December 13, 2019  
Individual/Entity: **Pizza Buffet**  
Facility: Pizza Buffet  
Location: 3420 Clemson Boulevard  
Anderson, SC 29621  
Mailing Address: Same  
County: Anderson  
Previous Orders: None  
Permit Number: 04-206-02096  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Pizza Buffet (Individual/Entity) is a restaurant located in Anderson, South Carolina. The Department conducted an inspection on November 5, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: obscured, covered, defaced, relocated, or removed the grade decal that was posted by the Department.

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**).

79) Order Type and Number: Consent Order 2019-206-04-043  
Order Date: December 13, 2019  
Individual/Entity: **Trading Post**  
Facility: Trading Post  
Location: 403 West 3<sup>rd</sup> Avenue  
Lake View, SC 29563  
Mailing Address: 2325 Dillon Highway  
Dillon, SC 29563  
County: Dillon  
Previous Orders: None  
Permit Number: 17-206-00717  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Trading Post (Individual/Entity) is a restaurant located in Lake View, South Carolina. The Department conducted inspections on November 27, 2018, December 4, 2018, and July 18, 2019. 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**).

80) Order Type and Number: Consent Order 2019-206-04-049  
Order Date: December 13, 2019  
Individual/Entity: **Dunkin Donuts**  
Facility: Dunkin Donuts  
Location: 2210 West Lucas Street  
Florence, SC 29501  
Mailing Address: 1230 Dickson Avenue  
Hanahan, SC 29410  
County: Florence  
Previous Orders: None  
Permit Number: 21-206-02638  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Dunkin Donuts (Individual/Entity) is a restaurant located in Florence, South Carolina. The Department conducted inspections on August 22, 2018, May 28, 2019, and June 7, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that during pauses in food preparation or dispensing, food preparation and dispensing utensils were stored in the food with their handles above the top of the 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 two hundred dollars (**\$200.00**).

81) Order Type and Number: Consent Order 2019-206-08-012  
Order Date: December 13, 2019  
Individual/Entity: **Brown Golf Leasing LLC**  
Facility: Brown Golf Leasing LLC  
Location: 40 Island West Drive  
Bluffton, SC 29910  
Mailing Address: Same  
County: Beaufort  
Previous Orders: None  
Permit Number: 07-206-09476  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Brown Golf Leasing LLC (Individual/Entity) is a restaurant located in Bluffton, South Carolina. The Department conducted inspections on February 19, 2019, March 1, 2019, and September 23, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

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 2019-206-01-079  
Order Date: December 16, 2019  
Individual/Entity: **Sodexo/Northside Elementary**  
Facility: Sodexo/Northside Elementary  
Location: 710 North Townville Street  
Seneca, SC 29678  
Mailing Address: P.O. Box 352  
Buffalo, NY 14240  
County: Oconee  
Previous Orders: None  
Permit Number: 37-206-01083  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Sodexo/Northside Elementary (Individual/Entity) operates a cafeteria located in Seneca, South Carolina. The Department conducted inspections on May 17, 2018, October 2, 2018, May 17, 2019, and October 25, 2019. 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, six hundred dollars (**\$1,600.00**).

83) Order Type and Number: Consent Order 2019-206-02-086  
Order Date: December 16, 2019  
Individual/Entity: **Golden Brown & Delicious**  
Facility: Golden Brown & Delicious  
Location: 1267 Pendleton Street  
Greenville, SC 29611  
Mailing Address: 702 Knollwood Drive  
Greenville, SC 29607  
County: Greenville  
Previous Orders: 2019-206-02-019 (\$800.00)  
Permit Number: 23-206-11461  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Golden Brown & Delicious (Individual/Entity) is a restaurant located in Greenville, South Carolina. The Department conducted inspections on May 23, 2018, February 13, 2019, and September 11, 2019. 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; failed to use effective methods to cool cooked time/temperature control for safety foods; and failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked.

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 fifty dollars (**\$1,250.00**).

84) Order Type and Number: Consent Order 2019-206-03-079  
Order Date: December 16, 2019  
Individual/Entity: **Luce Italian Cucina**  
Facility: Luce Italian Cucina  
Location: 1812 Augusta Highway  
Lexington, SC 29072  
Mailing Address: Same  
County: Lexington  
Previous Orders: 2018-206-03-160 (\$5,000.00)  
Permit Number: 32-206-05579  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Luce Italian Cucina (Individual/Entity) is a restaurant located in Lexington, South Carolina. The Department conducted an inspection on July 10, 2019. 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**).

85) Order Type and Number: Consent Order 2019-206-06-134  
Order Date: December 16, 2019  
Individual/Entity: **Burger King #1215**  
Facility: Burger King #1215  
Location: 501 South Kings Highway  
Myrtle Beach, SC 29577  
Mailing Address: P.O. Box 7971  
Madison, WI 53713  
County: Horry  
Previous Orders: 2019-206-06-112 (\$800.00)  
Permit Number: 26-206-11560  
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Burger King #1215 (Individual/Entity) is a restaurant located in Myrtle Beach, South Carolina. The Department conducted inspections on June 26, 2019, July 22, 2019, and August 14, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to provide water at a temperature of at least 100°F through a mixing valve or combination faucet at the handwashing sink(s); failed to ensure that except for containers holding food that can be readily and unmistakably recognized such as dry pasta, working containers holding food or food ingredients that are removed from their original packages for use in the food establishment, such as cooking oils, flour, herbs, potato flakes, salt, spices, and sugar shall be identified with the common name of the food; and failed to clean the physical facilities as often as necessary to keep them clean.

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**).

86) <u>Order Type and Number:</u>	Consent Order 2019-206-03-108
<u>Order Date:</u>	December 18, 2019
<u>Individual/Entity:</u>	<b>Kinyania's</b>
<u>Facility:</u>	Kinyania's
<u>Location:</u>	2020 Hampton Street Columbia, SC 29201
<u>Mailing Address:</u>	141 Fairlawn Court Columbia, SC 29203
<u>County:</u>	Richland
<u>Previous Orders:</u>	None
<u>Permit Number:</u>	40-206-03251
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-25

Summary: Kinyania's (Individual/Entity) is a restaurant located in Columbia, South Carolina. The Department conducted inspections on July 29, 2019, August 5, 2019, October 10, 2019, and October 16, 2019. 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 provide accurate thermometer for measuring temperature readings.

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**).

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



(x) ACTION/DECISION  
( ) INFORMATION

Date: February 13, 2020

To: S.C. Board of Health and Environmental Control

From: Bureau of Land and Waste Management

Re: **Notice of Proposed Regulation Amending R.61-63, *Radioactive Materials (Title A)***

## I. Introduction

The Bureau of Land and Waste Management (“Bureau”) proposes the attached Notice of Proposed Regulation amending R.61-63, *Radioactive Materials (Title A)*, for publication in the February 28, 2020, *South Carolina State Register* (“*State Register*”). Legal authority resides in S.C. Code Section 13-7-70 (Supp 2016), which designates the Department of Health and Environmental Control (“Department”) as the agency responsible for the control and regulation of radiation sources. The Administrative Procedures Act, S.C. Code Section 1-23-120(H)(1), exempts these amendments from General Assembly review, as the Department proposes these amendments for compliance with federal law.

## II. Facts


1. Pursuant to the Federal Atomic Energy Act of 1954, the United States Nuclear Regulatory Commission (“Commission”) enters into agreements with state governors allowing for state regulation of byproduct, source, and special nuclear materials. 42 U.S.C. Section 2121. The Commission enters into such agreements if it finds the state regulatory program is complying with applicable federal regulations. *Id.* To renew South Carolina’s ongoing agreement with the Commission, the Bureau requests approval to amend R.61-63, ensuring state standards comply with the Commission’s regulatory updates. The proposed amendments add clarifications or corrections to Part II of the regulation. Additionally, the proposed amendments authorize the Department to review their general licensees’ quality assurance program for the use of Commission-approved Type B packaging for transportation of radioactive material as required in NRC Regulation Title 10, Code of Federal Regulation (“CFR”) Part 71.
2. The Department had a Notice of Drafting published in the October 25, 2019, *State Register*. A copy of the Notice of Drafting appears herein as Attachment B. The Department received no public comments by the November 25, 2019, close of the public comment period.
3. The Bureau held a stakeholder meeting on November 14, 2019, with *Energy Solutions* to discuss the schedule and implementation process for the proposed amendments.
4. The Bureau submitted draft text of the proposed amendments to the Technical Advisory Radiation Control Council (“TARCC”) on January 7, 2020, for review. The Bureau received no comments from TARCC resulting from the review.
5. Appropriate Department staff conducted an internal review of the proposed amendments on January 14, 2020.

6. The Bureau also submitted copies of the proposed regulations to the Commission for a compatibility review on June 7, 2017. The Commission responded with comments dated July 25, 2017. The Bureau integrated these comments into the proposed amendments where applicable.

### III. Request for Approval

The Bureau respectfully requests the Board to grant approval of the attached Notice of Proposed Regulation for publication in the February 28, 2020, *State Register*.

  
\_\_\_\_\_  
Henry J. Porter  
Bureau Chief

  
\_\_\_\_\_  
Myra C. Reece  
Director

Attachments:

- A. Notice of Proposed Regulation
- B. Notice of Drafting published in the October 25, 2019, *State Register*

**ATTACHMENT A**

**STATE REGISTER NOTICE OF PROPOSED REGULATION  
FOR R.61-63, *Radioactive Materials (Title A)***

**February 13, 2020**

Document No. \_\_\_\_\_

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL  
CHAPTER 61**

Statutory Authority: 1976 Code Section 13-7-70

61-63. Radioactive Materials (Title A).

**Preamble:**

The federal Atomic Energy Act of 1954 enables the United States Nuclear Regulatory Commission (“Commission”) to enter into agreements with state governors allowing for state regulation of byproduct, source, and special nuclear material. 42 U.S.C. Section 2121. The Commission enters into such agreements if it finds the state regulatory program complies with applicable federal regulations. *Id.* To renew South Carolina’s ongoing agreement with the Commission, the Department of Health and Environmental Control (“Department”) proposes amendments to R.61-63 for compliance with the Commission’s federal regulatory updates. The proposed amendments add clarifications or corrections to Part II of the regulation. Additionally, the proposed amendments authorize the Department to review their general licensees’ quality assurance program for the use of Commission-approved Type B packaging for transportation of radioactive material as required in NRC Regulation Title 10, Code of Federal Regulation (“CFR”) Part 71.

The Administrative Procedures Act, S.C. Code Section 1-23-120(H)(1), exempts these amendments from General Assembly review, as the Department proposes these amendments for compliance with federal law.

The Department had a Notice of Drafting published in the October 25, 2019, South Carolina State Register.

**Section-by-Section Discussion of Proposed Amendments:**

2.22.5 through subparagraphs 2.22.5.5

Added to allow a general license for transportation of NRC-approved packages.

2.22.6 through subparagraphs 2.22.6.4.2

Added to allow a general license for transportation of foreign-approved packages.

2.22.7 through subparagraph 2.22.7.2

Added to require maintenance of records.

2.22.8 through subparagraphs 2.22.8.3

Added to describe the quality assurance requirements.

2.22.9 through subparagraphs 2.22.9.1

Added to describe the quality assurance organization.

2.22.10 through subparagraphs 2.22.10.3

Added to describe how changes are to be made to quality assurance program.

2.22.11 through subparagraphs 2.22.11.1  
Added to describe the quality assurance requirements.

**Notice of Public Hearing and Opportunity for Public Comment:**

Interested persons may submit comment(s) on the proposed amendments to Ms. Lynne Garner of the Bureau of Land and Waste Management; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; [garnerld@dhec.sc.gov](mailto:garnerld@dhec.sc.gov). To be considered, the Department must receive the comment(s) by 5:00 p.m. on March 30, 2020, the close of the comment period.

The S.C. Board of Health and Environmental Control will conduct a public hearing on the proposed amendments during its May 7, 2020, 10:00 a.m. meeting. Interested persons may make oral and/or submit written comments at the public hearing. Persons making oral comments should limit their statements to five (5) minutes or less. The meeting will take place in the Board Room of the DHEC Building, located at 2600 Bull Street, Columbia, S.C. 29201. Due to admittance procedures, all visitors must enter through the main Bull Street entrance and register at the front desk. The Department will publish a meeting agenda twenty-four (24) hours in advance indicating the order of its scheduled items at <http://www.scdhec.gov/Agency/docs/AGENDA.PDF>.

The Department publishes a Monthly Regulation Development Update tracking the status of its proposed new regulations, amendments, and repeals and providing links to associated State Register documents at <http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/>.

**Statement of Need and Reasonableness**

The following presents an analysis of the factors listed in 1976 Code Sections 1-23-115(C)(1)-(3) and (9)-(11):

**DESCRIPTION OF REGULATION:** 61-63, Radioactive Materials (Title A)

**Purpose:** The Department proposes amendments to R.61-63 for compliance with federal regulatory updates to 10 CFR Part 71. The Department proposes these amendments in order to renew South Carolina's ongoing agreement with the Commission.

**Legal Authority:** 1976 Code Section 13-7-70

**Plan for Implementation:** Upon taking legal effect, Department personnel will take appropriate steps to inform the regulated community of the amendments and any associated information. The DHEC Regulation Development Update (accessible at <http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/>) provides a summary of and link to these proposed amendments. Additionally, printed copies are available for a fee from the Department's Freedom of Information Office.

**DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:**

The Department proposes amendments to R.61-63 for compliance with the Commission's federal regulatory updates. The federal Atomic Energy Act of 1954 enables the Commission to enter into agreements with state governors allowing for state regulation of byproduct, source, and special nuclear material. 42 U.S.C. Section 2121. The Commission enters into such agreements if it finds the state

regulatory program complies with applicable federal regulations. The proposed amendments are needed in order to renew South Carolina's ongoing agreement with the Commission. The amendments are beneficial in that they ensure state oversight of required standards.

#### DETERMINATION OF COSTS AND BENEFITS:

Neither the state nor its political subdivisions will incur additional costs through implementation of this amendment. Existing staff and resources will be utilized to implement this amendment to the regulation. The amendment will not create any significant additional costs to the regulated community since requirements or changes to the regulations will be substantially consistent with the current guidelines and review guidelines utilized by the Department.

#### UNCERTAINTIES OF ESTIMATES:

None.

#### EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

These amendments seek to ensure an effective regulatory program for radioactive material users under state jurisdiction and protection of the public and worker from unnecessary exposure to ionizing radiation.

#### DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

None. Federal requirements will apply to all affected users. The proposed amendments eliminate possible duplicative or redundant requirements.

#### Text:

~~Indicates Matter Stricken~~

Indicates New Matter

61-63. Radioactive Materials (Title A).

Statutory Authority: Section 13-7-40 et seq., as amended, of the 1976 Code, namely the Atomic Energy and Radiation Control Act.

**Add 2.22.5 and subparagraphs 2.22.5.1 through 2.22.5.5 as shown.**

2.22.5 General License: NRC-approved package.

2.22.5.1 A general license is issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, Certificate of Compliance (CoC), or other approval has been issued by the NRC.

2.22.5.2 This general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the provisions of subpart H of 10 CFR 71.

2.22.5.3 Each licensee issued a general license under 2.22.5.1 of this section shall:

2.22.5.3.1 Maintain a copy of the NRC-issued CoC, or other approval of the package, and the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment;

2.22.5.3.2 Comply with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of subparts A, G, and H of 10 CFR 71; and

2.22.5.3.3 Submit in writing before the first use of the package to: ATTN: Document Control Desk, Director, Division of Spent Fuel Storage and Transportations, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in 10 CFR 71.1(a), the licensee's name and license number, and the package identification number specified in the package approval.

2.22.5.4 This general license applies only when the package approval authorizes use of the package under this general license.

2.22.5.5 For a Type B package or fissile material package, the design of which was approved by NRC before April 1, 1996, the general license is subject to the additional restrictions of 10 CFR 71.19.

**Add 2.22.6 and subparagraphs 2.22.6.1 through 2.22.6.4.2 as shown.**

2.22.6 General License: Use of foreign-approved package.

2.22.6.1 A general license is issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a package, the design of which has been approved in a foreign national competent authority certificate that has been revalidated by the DOT as meeting the applicable requirements of 49 CFR 171.23.

2.22.6.2 Except as otherwise provided in this section, the general license applies only to a licensee having a quality assurance program approved by the Department as satisfying the applicable provisions of subpart H of 10 CFR 71.

2.22.6.3 This general license applies only to shipments made to or from locations outside the United States.

2.22.6.4 Each licensee issued a general license under 2.22.6.1 of this section shall:

2.22.6.4.1 Maintain a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the CoC relating to the use and maintenance of the packaging and to the actions to be taken before shipment; and

2.22.6.4.2 Comply with the terms and conditions of the certificate and revalidation, and with the applicable requirements of subparts A, G, and H of 10 CFR 71.

**Add 2.22.7 and subparagraphs 2.22.7.1 through 2.22.7.2 as shown.**

2.22.7 Records.

2.22.7.1 The licensee shall make available to the Department for inspections, upon reasonable notice, all records required by this part. Records are only valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.

2.22.7.2 The licensee shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include results of the determinations required by 10 CFR 71.85; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification, and repair activities. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. These records must be retained for three (3) years after the life of the packaging to which they apply.

**Add 2.22.8 and subparagraphs 2.22.8.1 through 2.22.8.3 as shown.**

2.22.8 Quality assurance requirements.

2.22.8.1 Purpose. This subpart describes quality assurance requirements applicable to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this subpart, "Quality Assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality Assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each licensee is responsible for satisfying the quality assurance requirements that apply to its use of a packaging for the shipment of licensed material subject to this subpart.

2.22.8.2 Establishment of program. Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of 10 CFR 71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

2.22.8.3 Approval of program. Before the use of any package for the shipment of licensed material subject to this subpart, each licensee shall obtain Department approval of its quality assurance program. Each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied, by submitting the description to: ATTN: South Carolina Department of Health and Environmental Control, Division of Waste Management, 2600 Bull Street, Columbia, South Carolina 29201.

**Add 2.22.9 and subparagraph 2.22.9.1.**

2.22.9 Quality assurance organization.

2.22.9.1 The licensee shall be responsible for the establishment and execution of the quality assurance program. The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

**Add 2.22.10 and subparagraphs 2.22.10.1 through 2.22.10.3 as shown.**

2.22.10 Changes to quality assurance program.

2.22.10.1 Each quality assurance program approval holder shall submit a description of a proposed change to its Department-approved quality assurance program that will reduce commitments in the program

description as approved by the Department. The quality assurance program approval holder shall not implement the change before receiving Department approval.

2.22.10.1.1 The description of a proposed change to the Department-approved quality assurance program must identify the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the applicable requirements of subpart H of 10 CFR 71.

2.22.10.1.2 Reserved.

2.22.10.2 Each quality assurance program approval holder may change a previously approved quality assurance program without prior Department approval if the change does not reduce the commitments in the quality assurance program previously approved by the Department. Changes to the quality assurance program that do not reduce the commitments shall be submitted to the Department every twenty-four (24) months. In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, and non-substantive changes to punctuation or editorial items, the following changes are not considered reductions in commitment:

2.22.10.2.1 The use of a quality assurance standard approved by the Department that is more recent than the quality assurance standard in the licensee's current quality assurance program at the time of the change;

2.22.10.2.2 The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles, if there is no substantive change to either the functions of the position or reporting responsibilities;

2.22.10.2.3 The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text, if there is no substantive change to the functional relationships, authorities, or responsibilities;

2.22.10.2.4 The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the quality assurance program approval holder has committed to on record; and

2.22.10.2.5 Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

2.22.10.3 Each quality assurance program approval holder shall maintain records of quality assurance program changes.

**Add 2.22.11 and subparagraph 2.22.11.1 as shown.**

2.22.11 Quality assurance records.

2.22.11.1 The licensee shall maintain sufficient written records to describe the activities affecting quality. These records must include changes to the quality assurance program as required by 2.22.10 of this part, the instructions, procedures, and drawings required by 10 CFR 71.111 to prescribe quality assurance activities, and closely related specifications such as required qualifications or personnel, procedures, and equipment. The records must include the instructions or procedures that establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and



assigned responsibility. The licensee shall retain these records for three (3) years beyond the date when the licensee last engaged in the activity for which the quality assurance program was developed. If any portion of the quality assurance program, written procedures, or instructions is superseded, the licensee shall retain the superseded material for three (3) years after it is superseded.

## **ATTACHMENT B**

### **DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL CHAPTER 61**

Statutory Authority: 1976 Code Section 13-7-70

#### **Notice of Drafting:**

The Department of Health and Environmental Control (“Department”) proposes amendments to R.61 -63, Radioactive Materials (Title A). Interested persons may submit comment(s) on the proposed amendments to Ms. Lynne Garner of the Bureau of Land and Waste Management; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; [garnerld@dhec.sc.gov](mailto:garnerld@dhec.sc.gov). To be considered, the Department must receive comments no later than 5:00 p.m. on Monday, November 25, 2019, the close of the draft comment period.

#### **Synopsis:**

The United States Nuclear Regulatory Commission (NRC), promulgates amendments to NRC Regulation, Title 10, Code of Federal Regulations (CFR), throughout each calendar year. Recent amendments include revisions to transportation safety requirements and harmonization with the International Atomic Energy Agency Transportation requirements, including amendments to 10 CFR Part 71 (RATS ID 2015-3). These final rules were published in the Federal Register at 80 FR 33987 on June 12, 2015, and 80 FR 48683 on August 14, 2015. The Department proposes amending R.61 -63, Radioactive Materials (Title A) to incorporate the above federal regulations to maintain conformity with federal requirements found in 10 CFR Part 71 and to ensure compliance with federal standards as required by Section 274 of the Atomic Energy Act of 1954.

The Administrative Procedures Act, S.C. Code Section 1-23-120(H)(1), exempts this amendment from General Assembly review, as the Department proposes this amendment for compliance with federal law.

SUMMARY SHEET  
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

February 13, 2020

- ( X ) ACTION/DECISION  
( ) INFORMATION

**I. TITLE:** Request for Placement of Lasmiditan into Schedule V for Controlled Substances in South Carolina.

**II. SUBJECT:** Placement of Lasmiditan into Schedule V for Controlled Substances.

**II. FACTS:**

Controlled substances are governed by the Controlled Substances Act (“CSA”), Title 44, Chapter 53 of the S.C. Code of Laws. Schedule V substances are listed in Section 44-53-270. 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. 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.

South Carolina Code 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 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.

On October 11, 2019, the U.S. Food and Drug Administration (“FDA”) approved a new drug application for Reyvow (lasmiditan). Lasmiditan is chemically known as 2,4,6-trifluoro-*N*-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl)-benzamide. The federal Department of Health and Human Services (“HHS”) provided the federal Drug Enforcement Administration (“DEA”) with a recommendation that lasmiditan be placed in schedule V of the federal Controlled Substances Act (“federal CSA”). In accordance with the federal CSA, as revised by the Improving Regulatory Transparency for New Medical Therapies Act, the DEA issued an interim final rule placing lasmiditan (including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible) in schedule V of the

federal CSA, effective January 31, 2020, in *Federal Register*, Volume 85, Number 21, pages 5557-5562; <https://www.govinfo.gov/content/pkg/FR-2020-01-31/pdf/2020-01957.pdf>.

### III. ANALYSIS:

Lasmiditan (2,4,6-trifluoro-*N*-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl)-benzamide) is a new molecular entity with central nervous system (“CNS”) depressant properties. Lasmiditan is a 5-hydroxytryptamine (5-HT, serotonin) 1F receptor agonist. One of its metabolites has low GABA channel positive allosteric activity. On October 11, 2018, Eli Lilly and Company (“Sponsor”) submitted a new drug application (“NDA”) for lasmiditan to the FDA for Reyvow (lasmiditan) 50 and 100 mg oral tablets. On November 4, 2019, the DEA received notification that FDA approved, on October 11, 2019, the NDA for Reyvow (lasmiditan) for the acute treatment of migraine with or without aura in adults.

On November 4, 2019, the DEA received from the HHS a scientific and medical evaluation document dated October 23, 2019 prepared by the FDA related to lasmiditan. This document contained an eight-factor analysis of the abuse potential of lasmiditan, along with HHS’ recommendation to control lasmiditan under schedule V of the CSA. In response, the DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by the HHS, along with all other relevant data, and completed its own eight-factor review document pursuant to 21 U.S.C. 811(c). The DEA concluded that lasmiditan met the 21 U.S.C. 812(b)(5) criteria for placement in schedule V of the CSA.

21 U.S.C. 812(b) requires the evaluation of a substance’s abuse potential, accepted medical use, and safety for use under medical supervision for scheduling under the CSA as a controlled substance. After consideration of the above eight factors determinative of control of a substance (21 U.S.C. 811(c)), and a review of the scientific and medical evaluation and scheduling recommendation provided by HHS, DEA finds that lasmiditan meets the following criteria for placement in schedule V of the CSA pursuant to 21 U.S.C. 812(b)(5):

- 1) Lasmiditan has a low potential for abuse relative to the drugs or other substances in Schedule IV. Lasmiditan, a 5-HT<sub>1F</sub> receptor agonist, did not bind to receptors typically associated with abuse (e.g., opioid, cannabinoid, GABAergic). In the drug discrimination paradigm, lasmiditan did not generalize to the discriminative stimulus effects of the benzodiazepine lorazepam. Lasmiditan did, however, produce reinforcing effects in the self-administration assay. As detailed by HHS, in a human abuse-potential study, all doses of lasmiditan produced drug-liking scores that were significantly higher than that of placebo, indicating its abuse potential. Subjects following lasmiditan reported drug-liking scores that were significantly smaller than that of alprazolam (schedule IV drug), indicating that its abuse potential is less than that of alprazolam. Lasmiditan produced abuse-related adverse events to a greater extent than that of placebo, but with low frequency.
- 2) Lasmiditan has a currently accepted medical use in the United States. The FDA recently approved the NDA for lasmiditan oral tablets for the acute treatment of migraine with or without aura in adults. Therefore, lasmiditan has a currently accepted medical use in treatment in the United States.
- 3) Abuse of lasmiditan may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV. Lasmiditan may lead to physical or psychological dependence that is low relative to substances in schedule IV and similar to that of substances in schedule V.

**IV. RECOMMENDATION:**


The Acting Administrator of the DEA concludes that lasmiditan, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, warrants control in schedule V of the CSA.


Pursuant to South Carolina Code Section 44-53-160(C), the Department recommends the placement of lasmiditan in Schedule V for controlled substances in South Carolina and the amendment of Section 44-53-270 of the South Carolina Code of Laws to include:

( ) Lasmiditan (2,4,6-trifluoro-*N*-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl)-benzamide) including its salts, isomers, and salts of isomers.

The Department recommends the Board place lasmiditan in Schedule V of the South Carolina Controlled Substances Act.

Submitted by:

  
\_\_\_\_\_  
Lisa Thomson  
Chief  
Bureau of Drug Control

  
\_\_\_\_\_  
Gwen Thompson  
Interim Director  
Health Regulation

Attachment:  
*Federal Register*, Volume 85, Number 21, January 31, 2020

Thus, when the parties state in their “objection” that FDA’s “failure to indicate expressly that these substances no longer qualify in any way as ‘safe’ for use in food. . . amounts to an arbitrary and unlawful failure to protect the safety of food,” it does not appear the parties have stated with particularity a specific provision of the synthetic flavoring substances order that they deem objectionable. The parties do not object to our determination to revoke the uses of the synthetic flavoring substances, and in fact in their submission, the parties stated they “applaud FDA for acknowledging that it ‘cannot consider these synthetic flavoring substances to be safe as a matter of law’ ” (Earthjustice submission, page 1). Rather, by asserting in their submission that FDA is being arbitrary and unlawful by failing to indicate expressly in the final rule that substances found to induce cancer cannot qualify in any way as “safe” for use in food, we interpret the parties’ “objection” to be related to the petitioners’ request to establish zero tolerances for these synthetic flavoring additives, a request we declined to act on in the final rule because such a request was not the proper subject of a food additive petition.

As explained in the final rule (83 FR 50490 at 50491), a food additive petition must either propose the issuance of a regulation prescribing the conditions under which a food additive may be safely used or propose the amendment or repeal of an existing food additive regulation (sections 409(b)(1) and (i) of the FD&C Act). We explained in the final rule that we interpreted the request to establish zero tolerances for these flavoring additives as a request to issue a regulation prohibiting a substance from human food under part 189 and that this request fell outside the scope of a food additive petition because it does not propose the issuance of a new food additive regulation or the amendment or repeal of an existing food additive regulation (id.). Consequently, we did not address the zero tolerance request further in the final rule and thus this issue was not considered part of the order by regulation that revoked the uses for these synthetic flavoring additives, pursuant to section 409(c) of the FD&C Act. Therefore, because the parties failed to identify a provision of the order deemed objectionable and have also failed to raise an objection regarding the order made pursuant to section 409(c) or (d) of the FD&C Act, the provision for objections and public

hearing under section 409(f) of the FD&C Act does not apply.<sup>1</sup>

Finally, even though we do not think the parties’ submission legally rises to an objection under 409(f) of the FD&C Act, even if the submission was a properly raised objection, we would deny such an objection because the parties’ request amounts to the same outcome as the petitioners’ zero tolerance request and such a request falls outside the scope of the food additive petition process.

#### IV. Conclusion

After evaluating the submission from Earthjustice et al., we have concluded that the “objection” is not within the scope of the objections and hearing provision under section 409(f) of the FD&C Act. Therefore, we do not address the arguments related to this “objection.” We are confirming October 9, 2018, as the effective date of this regulation. FDA still intends to not enforce applicable requirements of the final rule with regard to food products manufactured (domestically and internationally) prior to October 9, 2020, that contain one or more of these six synthetic flavoring substances, to provide an opportunity for companies to reformulate products prior to enforcing the requirements of this final rule.

Dated: January 16, 2020.

**Lowell J. Schiller,**  
*Principal Associate Commissioner for Policy.*  
 [FR Doc. 2020–01060 Filed 1–30–20; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA–558]

#### Schedules of Controlled Substances: Placement of Lasmiditan in Schedule V

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Interim final rule with request for comments.

**SUMMARY:** On October 11, 2019, the U.S. Food and Drug Administration approved a new drug application for Reyvow (lasmiditan) tablets for oral use. Lasmiditan is chemically known as [2,4,6-trifluoro-*N*-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl)-benzamide]. Thereafter, the

<sup>1</sup> We note that the parties’ submission did not present any argument or evidence that FDA’s determination that the petitioners’ zero tolerance request was not the proper subject of a food additive petition, and was thus outside the scope of section 409 of the FD&C Act, was erroneous.

Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place lasmiditan in schedule V of the Controlled Substances Act (CSA). In accordance with the CSA, as revised by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing lasmiditan, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule V of the CSA.

**DATES:** The effective date of this rulemaking is January 31, 2020. Interested persons may file written comments on this rulemaking in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before March 2, 2020. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons may file a request for hearing or waiver of hearing in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.44. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before March 2, 2020.

**ADDRESSES:** To ensure proper handling of comments, please reference “Docket No. DEA–558” on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular

or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrisette Drive, Springfield, VA 22152.

- **Hearing requests:** All requests for hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrisette Drive, Springfield, Virginia 22152.

**FOR FURTHER INFORMATION CONTACT:** Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, VA 22152, Telephone: (571) 362-3261.

**SUPPLEMENTARY INFORMATION:**

**Posting of Public Comments**

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as

directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information, including the complete Department of Health and Human Services and Drug Enforcement Administration eight-factor analyses, to this interim final rule are available at <http://www.regulations.gov> for easy reference.

**Request for Hearing, or Waiver of Participation in Hearing**

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551-559, 21 CFR 1308.41-1308.45; 21 CFR part 1316, subpart D. Interested persons may file requests for a hearing, or notices of intent to participate in a hearing, in conformity with the requirements of 21 CFR 1308.44(a) or (b), and include a statement of interest in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing together with a written statement regarding the interested person's position on the matters of fact and law involved in any hearing as set forth in 21 CFR 1308.44(c).

All requests for a hearing and waivers of participation must be sent to DEA using the address information provided above.

**Background and Legal Authority**

Under the Improving Regulatory Transparency for New Molecular Therapies Act (Pub. L. 114-89), which was signed into law on November 25, 2015, the DEA is required to commence an expedited scheduling action with respect to certain new drugs approved by the U.S. Food and Drug Administration (FDA). As provided in 21 U.S.C. 811(j), this expedited scheduling is required where both of the following conditions apply: (1) The Secretary of the Department of Health and Human Services (Secretary of HHS

or the Secretary) has advised DEA that a New Drug Application (NDA) has been submitted for a drug that has a stimulant, depressant, or hallucinogenic effect on the central nervous system (CNS), and that it appears that such drug has an abuse potential; and (2) the Secretary recommends that DEA control the drug in schedule II, III, IV, or V, pursuant to 21 U.S.C. 811(a) and (b). In these circumstances, DEA is required to issue an interim final rule controlling the drug within 90 days.

The law further states that the 90-day timeframe starts the later of: (1) The date DEA receives the HHS scientific and medical evaluation/scheduling recommendation, or (2) the date DEA receives notice of the NDA approval by HHS. In addition, the law specifies that the rulemaking shall become immediately effective as an interim final rule without requiring DEA to demonstrate good cause therefor. Thus, the purpose of subsection (j) is to speed the process by which DEA schedules newly approved drugs that are currently either in schedule I or not controlled (but which have sufficient abuse potential to warrant control) so that such drugs may be marketed without undue delay following FDA approval.<sup>1</sup>

Subsection (j) further provides that the interim final rule shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, DEA must issue a final rule in accordance with the scheduling criteria of subsections 21 U.S.C. 811(b), (c), and (d) and 21 U.S.C. 812(b).

Lasmiditan [2,4,6-trifluoro-N-(6-[1-methylpiperidine-4-carbonyl]pyridine-2-yl)-benzamide] is a new molecular entity with central nervous system (CNS) depressant properties. Lasmiditan is a 5-hydroxytryptamine (5-HT, serotonin) 1F receptor agonist. One of its metabolites has low GABA<sub>A</sub> channel positive allosteric activity. On October 11, 2018, Eli Lilly and Company (Sponsor) submitted an NDA to FDA for Reyvow (lasmiditan) 50 and 100 mg oral tablets. On November 4, 2019, DEA received notification that FDA, on October 11, 2019, approved the NDA for Reyvow (lasmiditan), under section 505(c) of the FDCA, for the acute treatment of migraine with or without aura in adults.<sup>2</sup>

<sup>1</sup> Given the parameters of subsection (j), in DEA's view, it would not apply to a reformulation of a drug containing a substance currently in schedules II through V for which an NDA has recently been approved.

<sup>2</sup> [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2019/211280Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/211280Orig1s000ltr.pdf).

## Determination To Schedule Lasmiditan

On November 4, 2019, DEA received from HHS a scientific and medical evaluation document (dated October 23, 2019) prepared by the FDA related to lasmiditan. This document contained an eight-factor analysis of the abuse potential of lasmiditan, along with HHS' recommendation to control lasmiditan under schedule V of the CSA.

On December 4, 2019, the DEA requested clarification from HHS regarding supporting evidence for factors 6 and 7 listed in 21 U.S.C. 811(c), as well as the third finding under 21 U.S.C. 812(b)(5), for placement of lasmiditan in schedule V. HHS responded to the DEA via a letter on January 15, 2020, with the necessary clarification.

In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS, along with all other relevant data, and completed its own eight-factor review document pursuant to 21 U.S.C. 811(c). DEA concluded that lasmiditan met the 21 U.S.C. 812(b)(5) criteria for placement in schedule V of the CSA.

Pursuant to subsection 811(j), and based on the HHS recommendation, NDA approval by HHS/FDA, and DEA's determination, DEA is issuing this interim final rule to schedule lasmiditan as a schedule V controlled substance under the CSA.

Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in its scheduling action. Please note that both the DEA and HHS analyses are available in their entirety under "Supporting Documents" in the public docket for this interim final rule at <http://www.regulations.gov>, under Docket Number "DEA-558." Full analysis of, and citations to, the information referenced in the summary may also be found in the supporting and related material.

**1. Its Actual or Relative Potential for Abuse:** As noted by HHS, lasmiditan is a new molecular entity that has not been marketed in the United States or any other country. As a result, information on the actual abuse of lasmiditan is limited. According to HHS, lasmiditan is not currently available for medical treatment, lasmiditan has not been diverted from legitimate sources, and individuals have not taken the substance in amounts sufficient to create a hazard to public health and safety. DEA further notes that there are no reports for lasmiditan in the National Forensic Laboratory Information System

(NFLIS),<sup>3</sup> which collects drug identification results from drug cases submitted to and analyzed by State and local forensic laboratories. There were also no reports in STARLiMS,<sup>4</sup> DEA's laboratory drug evidence data system of record.

Data from HHS outlined in Factors 2 and 3 demonstrate that lasmiditan is a 5-hydroxytryptamine-1F (5-HT<sub>1F</sub>) receptor agonist. There are no 5-HT<sub>1F</sub> receptor agonists currently controlled in the CSA. Lasmiditan at the highest dose tested did produce reinforcing effects in a rat self-administration assay. Drug-liking visual analog scale (VAS) for lasmiditan were significantly higher than placebo and significantly lower than the schedule IV benzodiazepine alprazolam in an abuse potential study in humans (see Factor 3).

**2. Scientific Evidence of Its Pharmacological Effects, if Known:** According to HHS, lasmiditan functions as a 5-HT<sub>1F</sub> receptor agonist. HHS also further stated that lasmiditan does not bind to various other receptor targets (opioid, cannabinoid, GABAergic, or other ion channels) that are typically associated with abuse.

As shown by the studies summarized by HHS, lasmiditan did not produce abuse-related behaviors in the toxicity studies within mice, rats, and dogs. HHS stated that the studies demonstrating depressant effects such as weight loss, sedation, and hypothermia produced by lasmiditan could be due to its toxic concentrations of lasmiditan. In addition, results of the drug discrimination assay demonstrated that lasmiditan did not generalize to the discriminative stimulus effects of the benzodiazepine lorazepam (schedule IV); however, lasmiditan did produce reinforcing effects in the self-administration assay.

HHS described results from a Phase 1, randomized, double-blind, placebo-and active-controlled, crossover clinical trial in adult subjects who were recreational poly-drug users. The primary objective of this study was to assess the abuse potential of lasmiditan compared to alprazolam and placebo using the maximal effect score (E<sub>max</sub>) of the at-the-moment 100-mm bipolar Drug Liking VAS.

<sup>3</sup> NFLIS is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by State and local forensic laboratories in the United States. NFLIS data were queried on 11/14/2019.

<sup>4</sup> STARLiMS is a laboratory information management system that systematically collects results from drug chemistry analyses conducted by the DEA laboratories. On October 1, 2014, STARLiMS replaced STRIDE as the DEA laboratory drug evidence data system of record. STARLiMS data were queried on 11/18/2019.

Lasmiditan was evaluated by the comparison of Drug Liking E<sub>max</sub> between each dose of lasmiditan and placebo. All doses of lasmiditan (100 mg, 200 mg, and 400 mg) produced significantly higher E<sub>max</sub> than that of placebo indicating that lasmiditan has abuse potential. However, these effects of all doses of lasmiditan were significantly lower than alprazolam on mean E<sub>max</sub> of Drug Liking.

Lasmiditan 200 mg (therapeutic dose), lasmiditan 400 mg (supratherapeutic dose), and alprazolam 2 mg (43–49 percent) produced euphoric mood to a similar extent. The lower dose of lasmiditan (100 mg) produced euphoric moods in 25 percent of subjects. Alprazolam produced a feeling of relaxation in more subjects than that produced by any dose of lasmiditan. According to HHS, this pattern of adverse events (AEs) suggests that lasmiditan has a similar or slightly less potential for abuse than alprazolam.

According to HHS, the Sponsor conducted eighteen Phase 1 studies in which AEs, including abuse-related AEs, were evaluated. In Phase 1, single-dose studies with healthy subjects, lasmiditan produced somnolence, feeling drunk, and euphoric mood. Euphoric mood occurred in five out of twelve studies for lasmiditan, and one out of seven studies for a control group. According to HHS, overall, the data from Phase 1 studies indicated that lasmiditan had more abuse-related AEs than placebo, and alprazolam showed a greater incidence of abuse-related AEs as compared to lasmiditan in one study.

HHS reviewed data from five Phase 2 and 3 studies and stated that, at therapeutic doses, lasmiditan displays abuse-related AEs to a greater extent than placebo. However, these AEs occur at a low frequency (about one percent).

**3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance:** Appearing as a white to off-white solid, lasmiditan is highly soluble in water and freely soluble in methanol. Per HHS, none of the steps in the manufacturing process of lasmiditan produces or utilizes substances that have a known potential for abuse, nor can they be easily modified to generate a substance with abuse potential. A high level of expertise in and knowledge of organic chemistry is required to synthesize lasmiditan.

Rat studies demonstrate that lasmiditan has a half-life of approximately 31 hours. HHS also described lasmiditan pharmacokinetic data from another study conducted in beagle dogs in the fasted (overnight) state versus the fed state. The time measurement for maximal concentration



( $T_{max}$ ) was the only parameter that significantly differed between the fed (3.5 hours) and the fasted (1.25 hours) state, indicating that food has a significant slowing effect on the oral absorption of lasmiditan.

A separate study in male rats was conducted to compare the plasma and brain pharmacokinetic parameters, in addition to evaluating the bioavailability of lasmiditan. Results indicate that lasmiditan crosses the blood brain barrier and collects in the brain, producing exposure levels 2.5- to 3-fold higher than those in plasma. The  $T_{max}$  in both plasma and brain was reached in 30 minutes. However, the maximum serum concentration was two- and three-fold higher in the brain as compared to plasma levels following oral and IV administration, respectively. The oral bioavailability of the drug was 63.3 percent.

As described by HHS, an in-vitro study was conducted to identify the human cytochrome P450 isozymes responsible for the in-vitro metabolism of lasmiditan. Results indicated the possible involvement of CYP1A2 in the production of metabolites M7, M8, and M18; CYP2D6 and CYP2C9 in the production of M7 and M18; and CYP2C19 and CYP3A4 in the production of M7 and M18.

**4. Its History and Current Pattern of Abuse:** Lasmiditan was approved by FDA on October 11, 2019. According to HHS, as a single active ingredient in a drug product formulation, lasmiditan has not been approved for therapeutic use in any other country. There is no information available relating to the history and current pattern of abuse of this formulation of lasmiditan or the active ingredient. As stated in Factor 1, DEA notes that there has been no diversion of lasmiditan based on NFLIS and STARLiMS data.

**5. The Scope, Duration, and Significance of Abuse:** As described in Factor 4, lasmiditan as a single entity has not been approved for therapeutic use outside of the United States. A search by DEA of the NFLIS and STARLiMS databases found no evidence of law enforcement encounters of lasmiditan in the United States. Based on the preclinical and clinical study data described by HHS (see Factor 2, above), and on available epidemiological data, the scope, duration, and significance of lasmiditan abuse would likely be lower than substances in schedule IV of the CSA and similar to that of a drug controlled in schedule V.

**6. What, if Any, Risk There Is to the Public Health:** As stated by HHS, the extent to which a drug has abuse

potential is considered an indication of its public health risk. Based on the preclinical and clinical study data described by HHS (see Factor 2, above), lasmiditan has abuse potential and physical or psychological dependence (Factor 7) that is lower than substances in schedule IV of the CSA and similar to that of substances controlled in schedule V.

**7. Its Psychic or Physiological Dependence Liability:** HHS described an animal study that was conducted to assess the withdrawal effects of lasmiditan. Based on the data from the animal study, HHS concluded that lasmiditan does not produce signs consistent with physical dependence. HHS, in its clarification letter to DEA, stated that animal data, discussed in Factor 2, suggest that lasmiditan has the potential to produce psychological dependence less than that of substances in schedule IV and similar to that of substances in schedule V. HHS further added that these circumstances of uncertain physical dependence and limited psychological dependence have likewise been observed in their analyses of other schedule V drugs.

**8. Whether the Substance Is an Immediate Precursor of a Substance Already Controlled Under the CSA:** Lasmiditan is not an immediate precursor of a substance that is already controlled in the CSA as defined in 21 U.S.C. 802(23).

**Conclusion:** After considering the scientific and medical evaluation conducted by HHS, HHS' recommendation, and DEA's own eight-factor analysis, DEA has determined that these facts and all relevant data constitute substantial evidence of a potential for abuse of lasmiditan. As such, DEA hereby schedules lasmiditan as a controlled substance under the CSA.

#### Determination of Appropriate Schedule

21 U.S.C. 812(b) requires the evaluation of a substance's abuse potential, accepted medical use, and safety for use under medical supervision for scheduling under the CSA as a controlled substance. After consideration of the above eight factors determinative of control of a substance (21 U.S.C. 811(c)), and a review of the scientific and medical evaluation and scheduling recommendation provided by HHS, DEA finds that lasmiditan meets the following criteria for placement in schedule V of the CSA pursuant to 21 U.S.C. 812(b)(5).

**(1) Lasmiditan has a low potential for abuse relative to the drugs or other substances in Schedule IV.**

As stated by HHS, lasmiditan, a 5-HT<sub>1F</sub> receptor agonist, did not bind to receptors typically associated with abuse (e.g., opioid, cannabinoid, GABAergic). In the drug discrimination paradigm, lasmiditan did not generalize to the discriminative stimulus effects of the benzodiazepine lorazepam. Lasmiditan did, however, produce reinforcing effects in the self-administration assay.

As detailed by HHS, in a human abuse-potential study, all doses of lasmiditan produced drug-liking scores that were significantly higher than that of placebo, indicating its abuse potential. Subjects following lasmiditan reported drug-liking scores that were significantly smaller than that of alprazolam (schedule IV drug), indicating that its abuse potential is less than that of alprazolam. Lasmiditan produced abuse-related adverse events to a greater extent than that of placebo, but with low frequency (about 1 percent).

**(2) Lasmiditan has a currently accepted medical use in the United States.**

The FDA recently approved the NDA for lasmiditan oral tablets for the acute treatment of migraine with or without aura in adults. Therefore, lasmiditan has a currently accepted medical use in treatment in the United States.

**(3) Abuse of Lasmiditan may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV.**

As stated by HHS, based on the totality of the available scientific data, lasmiditan may lead to physical or psychological dependence that is low relative to substances in schedule IV and similar to that of substances in schedule V.

Based on these findings, the Acting Administrator of DEA concludes that lasmiditan warrants control in schedule V of the CSA. 21 U.S.C. 812(b)(5).

#### Requirements for Handling Lasmiditan

Lasmiditan is subject to the CSA's schedule V regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importing, exporting, research, and conduct of instructional activities and chemical analysis with, and possession involving, schedule V substances, including the following:

**1. Registration.** Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses)

lasmiditan, or who desires to handle lasmiditan, 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. Any person who currently handles or intends to handle lasmiditan, and is not registered with the DEA, must submit an application for registration and may not continue to handle lasmiditan, unless the DEA has approved that application for registration, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of Stocks.* Any person who does not desire, or is not able to obtain, a schedule V registration must surrender all quantities of currently held lasmiditan, or may transfer all quantities of currently held lasmiditan to a person registered with the DEA in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* Lasmiditan is subject to schedule III–V security requirements and must be handled and stored in accordance with 21 CFR 1301.71–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of lasmiditan must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

5. *Inventory.* Every DEA registrant who possesses any quantity of lasmiditan must take an inventory of lasmiditan on hand, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who becomes registered with the DEA to handle lasmiditan must take an initial inventory of all stocks of controlled substances (including lasmiditan) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including lasmiditan) on hand every two years, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant must maintain records and submit reports for lasmiditan, or products containing lasmiditan, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317.

7. *Prescriptions.* All prescriptions for lasmiditan, or products containing lasmiditan, must comply with 21 U.S.C.

829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

8. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule V controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of lasmiditan may only be for the legitimate purposes consistent with the drug's labeling, or for research activities authorized by the Federal Food, Drug, and Cosmetic Act and the CSA.

9. *Importation and Exportation.* All importation and exportation of lasmiditan must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving lasmiditan not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

## Regulatory Analyses

### Administrative Procedure Act

Section 553 of the Administrative Procedure Act (APA) (5 U.S.C.) generally requires notice and comment for rulemakings. However, 21 U.S.C. 811 provides that in cases where a certain new drug is (1) approved by HHS and (2) HHS recommends control in CSA schedule II–V, DEA shall issue an interim final rule scheduling the drug within 90 days. Additionally, the law specifies that the rulemaking shall become immediately effective as an interim final rule without requiring DEA to demonstrate good cause.

*Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs*

In accordance with 21 U.S.C. 811(a) and (j), this scheduling action is subject to formal rulemaking procedures performed “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

This final rule is not an Executive Order 13771 regulatory action pursuant

to Executive Order 12866 and OMB guidance.<sup>5</sup>

### Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

### Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does 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.

### Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

### Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA. Under 21 U.S.C. 811(j), DEA is not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply.

### Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined that this action would not result in any Federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year.” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

<sup>5</sup> Office of Mgmt. & Budget, Exec. Office of the President, Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017 Titled “Reducing Regulation and Controlling Regulatory Costs” (Feb. 2, 2017).

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This rule will not result in: An annual effect on the economy of \$100,000,000 or more; a

major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign-based companies in domestic and export markets. However, pursuant to the CRA, DEA has submitted a copy of this interim final rule to both Houses of Congress and to the Comptroller General.

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, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. Amend § 1308.15 by:

■ a. Redesignating paragraph (e)(4) as (e)(5);

■ b. Adding new paragraph (e)(4).

The addition reads as follows:

§ 1308.15 Schedule V.

\* \* \* \* \*

(e) \* \* \*

(4) Lasmiditan [2,4,6-trifluoro-N-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide) ..... 2790

\* \* \* \* \*

Dated: January 28, 2020.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2020–01957 Filed 1–30–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 3280 and 3282

[Docket No. FR 6018–F–02]

RIN 2502–AJ42

Streamlining and Aligning Formaldehyde Emission Control Standards for Certain Wood Products in Manufactured Home Construction With Title VI of the Toxic Substance Control Act

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Final rule.

SUMMARY: HUD is issuing a final rule to implement the Formaldehyde Standards for Composite Wood Products Act of 2010, which added Title VI to the Toxic Substances Control Act (TSCA). The purpose of TSCA Title VI is to reduce exposures to formaldehyde emissions from composite wood products, thereby resulting in benefits from avoided adverse health effects. In addition, HUD is removing certain aspects of the current manufactured housing formaldehyde standards requirements that are not addressed by TSCA. This final rule follows publication of a March 22, 2019, proposed rule and takes into consideration the public comments

received on the proposed rule. This final rule also incorporates by reference, ASTM D6007–14 and ASTM E1333–14, the current standard requirements for formaldehyde concentration and emissions rate air chamber testing.

DATES: This final rule is effective March 2, 2020. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of March 2, 2020.

FOR FURTHER INFORMATION CONTACT: Teresa B. Payne, Acting Administrator, Office of Manufactured Housing Programs, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; telephone 202–402–5365 (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8389 (toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background—HUD’s March 22, 2019 Proposed Rule

The Formaldehyde Standards for Composite Wood Products Act of 2010, which added TSCA Title VI (Pub. L. 111–199, enacted on July 7, 2010) (“Formaldehyde Act of 2010”), established new formaldehyde emissions standards for all hardwood plywood, medium-density fiberboard, and particleboard, including when incorporated into finished goods, that are sold, supplied, offered for sale, or manufactured (including imported) in the United States. TSCA Title VI directs HUD to update its regulation addressing formaldehyde emission standards to ensure consistency with the standards in TSCA not later than 180 days after

the Environmental Protection Agency (EPA) promulgates regulations. EPA’s final rule implementing the new requirements became effective May 22, 2017. See 81 FR 89674.

On March 22, 2019, HUD published a proposed rule in the Federal Register, at 84 FR 10738, to streamline and align formaldehyde emission control standards requirements for certain wood products in manufactured homes with Title VI of the Toxic Substance Control Act. The rule proposed revising HUD’s current formaldehyde emission standards for composite wood products used in manufactured housing at 24 CFR parts 3280 and 3282 to ensure consistency with the requirements established by section 601 of TSCA and EPA requirements, including the scope of products tested and processes for testing.

In addition, HUD proposed to remove certain aspects of HUD’s manufactured housing formaldehyde standards requirements that are not addressed by TSCA, including provisions for a health notice to be posted in every manufactured home, testing of panels treated after certification, and testing of certain plywood materials. Lastly, HUD’s proposed rule also added the EPA required provision for labeling finished goods by requiring labeling of each manufactured home as being “TSCA Title VI compliant” to the data plate of each manufactured home in 24 CFR 3280.5,<sup>1</sup> as recommended by the

<sup>1</sup> On October 25–27, 2016, HUD held a meeting with the Manufactured Housing Consensus Committee (MHCC). See 81 FR 66288. The Committee voted to accept a working draft of the proposed rule which cross-referenced EPA’s requirements in HUD’s regulations and removed the health hazard warning requirement in 24 CFR 3280.309. See Minutes MHCC Meeting October 25–