

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

June 29, 2022

- () ACTION/DECISION
(X) INFORMATION

- I. TITLE:** Healthcare Quality Administrative and Consent Orders.
- II. SUBJECT:** Healthcare Quality Administrative Orders and Consent Orders for the period of April 1, 2022, through April 30, 2022.
- III. FACTS:** For the period of April 1, 2022, through April 30, 2022, Healthcare Quality reports one (1) Administrative Order and seven (7) Consent Orders totaling \$33,300 in assessed monetary penalties.

Name of Bureau	Facility, Service, Provider, or Equipment Type	Administrative Orders	Consent Orders	Assessed Penalties	Required Payment
Community Care	Community Residential Care Facility (CRCF)	1	2	\$15,000	\$15,000
Radiological Health	Radioactive Material Industrial Licensee	0	1	\$5,000	\$5,000
	Chiropractic X-Ray Facility	0	1	\$1,700	\$425
	Dental X-Ray Facility	0	1	\$1,700	\$425
	Medical X-Ray Facility	0	1	\$9,000	\$2,250
Healthcare Systems and Services	Paramedic	0	1	\$900	\$900
TOTAL		1	7	\$33,300	\$24,000

Submitted By:

Gwendolyn C. Thompson

Gwen C. Thompson
Deputy Director
Healthcare Quality

HEALTHCARE QUALITY ENFORCEMENT REPORT
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

June 29, 2022

Bureau of Community Care

Facility Type	Total Number of Licensed Facilities	Total Number of Licensed Beds
Community Residential Care Facility (CRCF)	475	21,698

1. Pageland Care Facility – Pageland, SC

Inspections and Investigations: The Department conducted complaint investigations in February 2021 and September 2021, a routine inspection in May 2021, and routine follow-up inspections in July 2021, October 2021, and November 2021, and found the facility violated regulatory requirements.

Violations: The Department found the facility violated Regulation 61-84, *Standards for Licensing Community Residential Care Facilities*, by failing to have documentation of a criminal background check for a staff member and by not conducting a criminal background check for a staff member prior to employment. The Department further found the facility failed to:

- Render care and services in accordance with orders from physicians for administering medications.
- Complete annual physical examinations for a resident.
- Have residents’ physician-ordered medications available for administration.
- Properly initial the medication administration records (MARs) as medications were administered.
- Have documented reviews of the MARs at each shift change by outgoing staff members with incoming staff members.
- Maintain records of receipt, administration, and disposition of all controlled substances in sufficient detail to enable an accurate reconciliation.
- Have documented reviews of the control sheets at each shift change by outgoing staff members with incoming staff members.
- Have a written plan to be implemented to ensure the continuation of essential resident support services.
- Promote conditions that prevent the spread of infectious, contagious, and/or communicable diseases in compliance with guidelines from the Centers for Disease Control and Prevention (CDC).
- Have documentation of the second step of a staff member’s two-step Tuberculin Skin Test (TST).
- Ensure a resident admitted with only the first step of the TST completed the second step within 14 days of admission.
- Ensure the facility was free of vermin and offensive odors.
- Ensure that each specific interior area of the facility was clean.

Moreover, the facility failed to maintain plumbing fixtures that require hot water at a temperature between 100 degrees Fahrenheit and 120 degrees Fahrenheit.

Enforcement Action: The parties agreed to resolve the matter with a consent order. The parties executed a consent order imposing a civil monetary penalty of \$12,000 against the facility. The facility was required to pay the assessed monetary penalty within thirty (30) days after the execution of the Consent Order.

Remedial Action: The facility has made the required payment, in full, totaling \$12,000.

Prior Orders: None in the last five (5) years.

2. MIRCI Group Home I – Columbia, SC

Inspections and Investigations: The Department conducted an investigation in August 2021 and found the facility violated regulatory requirements.

Violations: The Department found the facility violated Regulation 61-84, *Standards for Licensing Community Residential Care Facilities*, by failing to implement its policies and procedures regarding “Abuse, Neglect, and Exploitation of Persons Served and Crisis Intervention Engagement.” Moreover, the facility failed to ensure a resident was treated with dignity and respect as defined by the Bill of Rights for Residents of Long-Term Care Facilities, S.C. Code Section 44-81-40(G).

Enforcement Action: The parties agreed to resolve the matter with a consent order. The parties executed a consent order imposing a civil monetary penalty of \$3,000 against the facility. The facility was required to pay the assessed monetary penalty within thirty (30) days after the execution of the Consent Order.

Remedial Action: The facility has made the required payment, in full, totaling \$3,000.

Prior Orders: None in the last five (5) years.

3. Oakridge Community Care Home #1 – Inman, SC

Inspections and Investigations: On February 14, 2022, the South Carolina Attorney General’s Office, Medicaid Fraud Control Unit (MFCU), notified the Department regarding the arrest of the administrator for multiple counts of committing neglect and exploitation of vulnerable adults as well as breach of trust with fraudulent intent. Upon this notification from the MFCU, the Department inspected the facility. The Department observed and cited regulatory violations as a result of the inspection.

Violations: The Department found the facility violated Regulation 61-84, *Standards for Licensing Community Residential Care Facilities*, by failing to have documentation of criminal background checks for newly hired staff members. The Department further found the facility failed to:

- Have documentation of accurate and current information for staff members, to include personal, work, and training background.
- Have in writing assigned duties and responsibilities for all staff members and direct care volunteers in writing.
- Have documentation of initial and/or annual basic first-aid training for all staff members.
- Have documentation of initial and/or annual vital sign training for the designated staff members.
- Have documentation of initial and/or annual contagious and/or communicable disease training for all staff members.
- Have documentation of initial and/or annual medication training for all staff members.

- Have documentation of initial and/or annual specific care training for all staff members.
- Have documentation of initial and/or annual use of restraint techniques training for all staff members.
- Have documentation of initial and/or annual OSHA standards regarding blood-borne pathogens training for all staff members.
- Have documentation of initial and/or annual CPR training for the designated staff members.
- Have documentation of initial and/or annual confidentiality of resident information and records for all staff members.
- Have documentation of initial and/or annual Bill of Rights for Residents of Long-Term Care Facilities training for all staff members.
- Have documentation of initial and/or annual fire response training for all staff members.
- Have documentation of initial and/or annual emergency procedures and disaster preparedness training for all staff members.
- Have documentation of initial and/or annual activity training for the designated staff members.
- Have health assessments, including two-step Tuberculin Skin Tests, for staff members.
- Render care and services in accordance with physicians' orders.
- Have available medications, including controlled substances, and medical supplies as ordered by physicians.
- Properly initial Medication Administration Records (MARs) as medications were administered.
- Have documented review of MARs at each shift change.
- Ensure all medications were kept in the original containers or packaging.
- Ensure that expired medications were not stored with current medications.
- Maintain records of controlled substances in sufficient detail to enable an accurate reconciliation.
- Have documented reviews of the controlled sheets at each shift change.
- Ensure that food prepared on-site complied with the requirements of Regulation 61-25, *Retail Food Establishments*.
- Maintain all equipment and building components in good repair and operating condition.
- Ensure the facility was clean and free from vermin and offensive odors.
- Ensure each interior area of the facility was clean.
- Ensure all exterior areas of the facility were clean.
- Store linen and clothing in a manner to prevent contamination.

Moreover, the facility failed to ensure liquid soap and a sanitary mean of drying hands were provided in each lavatory used by more than one resident and by allowing communal use of bar soap.

Enforcement Action: On February 15, 2022, the Department issued an emergency suspension order immediately suspending the license of Oakridge #1 based upon its determination that conditions and practices existed that constituted an immediate threat to the health, safety, and welfare of the residents. Pursuant to S.C. Code Section 44-7-320(A)(3), the South Carolina Administrative Law Court (ALC) held a hearing on February 18, 2022, to determine whether the immediate threatening conditions and practices continued to exist. On March 1, 2022, the ALC issued its order upholding the emergency suspension. By certified letter dated March 14, 2022, the Department notified the facility that it was considering an enforcement action. The Department requested the facility attend an enforcement conference on March 29, 2022, to discuss the violations. The facility did not appear at the March 29, 2022, enforcement conference. As a result of the foregoing, the Department decided to issue an administrative order revoking the facility's license.

Remedial Action: All thirty-seven (37) residents were relocated as of February 17, 2022.

Prior Orders: The Department took enforcement action against the facility in October 2017. The parties agreed to resolve the matter with a consent order imposing a monetary penalty of \$15,000. The facility agreed to pay \$7,500 of the assessed monetary penalty within thirty (30) days of execution of the Consent Order. The remaining \$4,500 was held in abeyance upon a six-month substantial compliance period. The facility attended a compliance assistance meeting with the Department.

The Department issued an administrative order against the facility in January 2022 based on several repeated regulatory violations. The Administrative Order required the facility to pay a civil monetary penalty of \$19,000 within 30 days of the issuance of the Administrative Order. The facility did not pay the \$19,000 civil monetary penalty.

Bureau of Radiological Health

License Type	Total Number of Licensees
Radioactive Material Industrial Licensee	136

4. S&ME, Inc. – Mount Pleasant, SC

Inspections and Investigations: On August 31, 2021, the Department was notified that one of the licensee’s vehicles was stolen while containing licensed radioactive material. The Department conducted an investigation of the licensee in September 2021 and found the licensee violated regulatory requirements.

Violations: The Department found the licensee failed to comply with Regulation 61-63, *Radioactive Materials (Title A)*, by failing to control and maintain constant surveillance of material not in storage and located in an unrestricted area. The licensee’s authorized gauge user stopped and pulled the vehicle to the side of the road to inspect an item in the area and got out of the vehicle while it was still running. The gauge user then proceeded to walk approximately seventy-five feet (75 ft.) away from the vehicle to inspect the item in the area. As the gauge user was performing the inspection, he heard the vehicle rapidly accelerating behind him and saw that the vehicle had been taken from the side of the road. The vehicle was recovered later that day along with the licensed radioactive material. The licensee inspected the licensed radioactive material and determined that it had not been tampered with nor were there any signs of damage.

Enforcement Action: The parties agreed to resolve the matter with a consent order. The parties executed a consent order imposing a civil monetary penalty of \$5,000 against the licensee. The licensee was required to pay the assessed penalty within thirty (30) days of execution of the Consent Order.

Remedial Action: The licensee has made the required payment, in full, totaling \$5,000.

Prior Orders: None in the past five (5) years.

Registrant Type	Total Number of Registered Facilities
Chiropractic X-Ray Facility	492

5. Gittens Chiropractic Clinic, PA. – Florence, SC

Inspections and Investigations: The Department conducted a routine inspection of the registrant in July 2021 and found the registrant violated regulatory requirements.

Violations: The Department found the registrant failed to comply with Regulation 61-64, *X-rays (Title B)*, by failing to conduct performance testing on medical radiographic x-ray systems annually, a repeat violation. The registrant failed to conduct equipment performance testing for 2019 and 2020.

Enforcement Action: The parties agreed to resolve the matter with a consent order. The parties executed a consent order imposing a civil monetary penalty of \$1,700 against the registrant. The registrant was required to pay \$425 of the assessed monetary penalty within thirty (30) days of executing the Consent Order. The remaining balance of \$1,275 is stayed upon the timely payment of the \$425 and a 24-month compliance period.

Remedial Action: The registrant has made the required payment, in full, totaling \$425.

Prior Orders: None in the past five (5) years.

Registrant Type	Total Number of Registered Facilities
Dental X-Ray Facility	1,797

6. Dental Implant Centre – Mount Pleasant, SC

Inspections and Investigations: The Department conducted a routine inspection of the registrant in July 2021 and found the registrant violated regulatory requirements.

Violations: The Department found the registrant failed to comply with Regulation 61-64, *X-rays (Title B)*, by failing to conduct equipment performance testing on dental x-ray systems (excluding dental computed tomography and dental hand-held systems) biennially, a repeat violation. The registrant failed to conduct equipment performance testing on the dental intraoral x-ray systems in 2011, 2016, and 2018.

Enforcement Action: The parties agreed to resolve the matter with a consent order. The parties executed a consent order imposing a civil monetary penalty of \$1,700 against the registrant. The registrant was required to pay \$425 of the assessed monetary penalty within thirty (30) days of executing the Consent Order. The

remaining balance of \$1,275 is stayed upon the timely payment of the \$425 and a 36-month compliance period.

Remedial Action: The registrant has made the required payment, in full, totaling \$425.

Prior Orders: None in the past five (5) years.

Registrant Type	Total Number of Licensed Facilities
Medical X-Ray Facility	932

7. R. Bauer Vaughters III, MD, Inc. – Aiken, SC

Inspections and Investigations: The Department conducted a routine inspection of the registrant in June 2021 and found the registrant violated regulatory requirements.

Violations: The Department found the registrant failed to comply with Regulation 61-64, *X-rays (Title B)*, by failing to assure operation of its bone density x-ray system by technicians certified by the South Carolina Quality Standards Association, a repeat violation. The registrant allowed non-certified persons to operate the bone density x-ray system.

Enforcement Action: The parties agreed to resolve the matter with a consent order. The parties executed a consent order imposing a civil monetary penalty of \$9,000. The registrant was required to pay \$2,250 of the assessed monetary penalty within thirty (30) days of executing the Consent Order. The remaining balance of \$6,750 is stayed pending timely payment of the required \$2,250.

Remedial Action: The registrant has made the required payment, in full, totaling \$2,250.

Prior Orders: None in the past five (5) years.

Bureau of Healthcare Systems and Services

Level of Certification	Total Number of Certified Paramedics
Paramedic	4,131

8. Timothy Godwin – Paramedic

Inspections and Investigations: The Department conducted an investigation in May 2021 and found that the paramedic was in violation of regulatory requirements.

Violations: The Department determined that the paramedic was in violation of Regulation 61-7, *Emergency Medical Services*, for committing misconduct, as defined in S.C. Code Section 44-61-80(F)(6), by disregarding an appropriate order by a physician concerning emergency treatment and transportation. The paramedic failed to follow medical control protocols by not starting an intravenous fluid (IV) and administering a fluid bolus of normal saline as indicated for a patient displaying signs and symptoms of hyperglycemia. Mr. Godwin also committed misconduct, as defined in S.C. Code Section 44-61-80(F)(8), while at the scene, the paramedic discontinued care or abandoned the patient without the patient's consent or without providing for further administration of care, by an equal or higher medical authority. Moreover, the paramedic committed misconduct as defined in S.C. Code Section 44-61-80(F), by failing to provide a patient medical treatment of a quality deemed acceptable by the Department, by failing to treat the patient in accordance with protocol and by delaying patient transport to the hospital by diverting to the ambulance station and handing the patient over to another paramedic instead of transporting the patient to the appropriate hospital.

Enforcement Action: The parties agreed to resolve the matter with a consent order. The parties executed a consent order assessing a monetary penalty of \$900 against the paramedic. The paramedic is required to pay the full amount of the assessed monetary penalty within thirty (30) days of execution of the Consent Order. The paramedic agrees to successfully complete a Professional Ethics and Personal Leadership (PEPL) class as determined by the Department and a refresher class in Advanced Cardiac Life Support (ACLS) within six months of the execution of the Consent Order. The paramedic shall also be demoted to an Advanced Emergency Medical Technician (AEMT) and his paramedic certification suspended for a period of two years upon execution of the Consent Order.

Remedial Action: The paramedic made the required payment, in full, totaling \$900. The paramedic has been issued an AEMT certification. The paramedic has not yet completed the PEPL class or ACLS refresher class.

Prior Orders: None in past five (5) years.

SUMMARY SHEET
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
June 29, 2022

_____ 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 April 1, 2022, through May 31, 2022.
3. **FACTS:** For the reporting period of April 1, 2022, through May 31, 2022, the Office of Environmental Affairs issued seventy-five (75) Consent Orders with total assessed civil penalties in the amount of three hundred fifty-seven thousand, three hundred forty-six dollars and nine cents (\$375,346.09). Also, sixteen (16) Administrative Orders with total assessed civil penalties in the amount of eighty-nine thousand, nine hundred five dollars (\$89,905.00) were reported during this period.

Bureau and Program Area	Administrative Orders	Assessed Penalties	Consent Orders	Assessed Penalties
Land and Waste Management				
UST Program	4	\$67,605.00	12	\$60,270.00
Aboveground Tanks	0	0	0	0
Solid Waste	1	\$21,300.00	1	\$2,580.00
Hazardous Waste	0	0	2	\$21,000.00
Infectious Waste	0	0	4	\$185,300.00
Mining	0	0	1	\$600.00
SUBTOTAL	5	\$88,905.00	20	\$269,750.00
Water				
Recreational Water	0	0	2	\$1,080.00
Drinking Water	0	0	5	\$2,000.00
Water Pollution	0	0	10	\$40,266.09
Dam Safety	0	0	0	0
SUBTOTAL	0	0	17	\$43,346.09
Air Quality				
SUBTOTAL	0	0	2	\$5,000.00
Environmental Health Services				
Food Safety	1	\$1,000.00	32	\$34,750.00
Onsite Wastewater	10	0	4	\$4,500.00
SUBTOTAL	11	\$1,000.00	36	\$39,250.00
OCRM				
SUBTOTAL	0	0	0	0
TOTAL	16	\$89,905.00	75	\$357,346.09

Submitted by:



Myra C. Reece
Director of Environmental Affairs

**ENVIRONMENTAL AFFAIRS ENFORCEMENT REPORT
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
June 29, 2022**

BUREAU OF LAND AND WASTE MANAGEMENT

Underground Storage Tank Enforcement

- 1) Order Type and Number: Administrative Order 21-0349-UST
Order Date: March 21, 2022
Individual/Entity: **Energy Distribution, LLC**
Facility: Energy Distribution
Location: 1500 Buncombe Street
Greenville, SC 29615
Mailing Address: Same
County: Greenville
Previous Orders: None
Permit/ID Number: 10885
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, 280.31(c), 280.34(c), 280.35(a)(2), 280.36(a)(1)(i), 280.36(a)(1)(ii), 280.40(a), 280.40(a)(3), 280.41(b)(1)(i)(B), 280.43(d), 280.44(a), 280.45(b)(1), 280.242(b)(3), 280.242(b)(4), 280.243(c), and 280.245(2012 and Supp. 2020).

Summary: Energy Distribution, LLC (Individual/Entity) owns and operates underground storage tanks (USTs) in Greenville County, South Carolina. On May 27, 2021, the Department conducted an inspection and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to inspect the impressed current system every sixty (60) days; failed to provide records to the Department upon request; failed to test overfill prevention equipment at least once every three (3) years to ensure the overfill prevention equipment is set to activate at the correct level specified in Section 280.20(c); failed to check and document monthly required equipment walkthrough inspections; failed to check and document annually required equipment walkthrough inspections; failed to provide an adequate release detection method; failed to annually test release detection equipment for proper operation; failed to conduct an annual line tightness test or monitor pressurized piping monthly; failed to conduct automatic tank gauging (ATG) properly; failed to check line leak detector function annually; failed to maintain results of annual operation tests for three (3) years; failed to validate that monthly requirements have been met; failed to physically visit each assigned facility once a quarter; failed to train Class C operators before they assume responsibility for the UST facility; and failed to designate and list all Class C operators.

Action: The Individual/Entity is required to submit: either the most recent twelve (12) months of ATG records for all USTs at the Facility or tank tightness test results for all USTs at the Facility and a current passing ATG record for all USTs; line tightness test results for all USTs; line leak detector function check test results for all USTs; release

detection operability test results for all USTs; overfill prevention equipment operability test results for all UST overfill devices; proof an impressed current rectifier log has been initiated and is being properly maintained; and a list of Class C Operators trained and designated for the Facility by May 24, 2022. The Department has assessed a total civil penalty in the amount of fourteen thousand, nine hundred seventy dollars (\$14,970.00). The Individual/Entity shall pay a civil penalty in the amount of fourteen thousand, nine hundred seventy dollars (**\$14,970.00**) by May 24, 2022.

Update: No Request for Review was filed; therefore, the effective date of the Order is April 9, 2022. This will be referred to Office of General Counsel for further action.

2) Order Type and Number: Administrative Order 21-0601-UST
Order Date: March 21, 2022
Individual/Entity: **Virenkumar Patel**
Facility: Friarsgate Supermart
Location: 100 North Royal Tower Drive
Irmo, SC 29063-2781
Mailing Address: 236 River Bridge Lane
Lexington, SC 29073
County: Richland
Previous Orders: None
Permit/ID Number: 12482
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, 280.30(a), 280.36(a)(1)(ii), 280.40(a), 280.41(b)(1)(i)(B), 280.43(d), 280.44(a), 280.93(a), and 280.110(c) (2012 and Supp. 2020).

Summary: Virenkumar Patel (Individual/Entity) owns and operates underground storage tanks (USTs) in Richland County, South Carolina. On June 2, 2021, the Department conducted an inspection and issued a Notice of Alleged Violation to Rashmika Patel. On September 14, 2021, the Department received notification that a transfer of ownership had occurred naming Virenkumar Patel as the new owner of the USTs. The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to maintain spill/overfill prevention equipment; failed to check and document annually required equipment walkthrough inspections; failed to provide an adequate release detection method; failed to conduct annual tightness test or have monthly monitoring of pressurized piping; failed to conduct automatic tank gauging properly; failed to conduct annual test of automatic line leak detectors; failed to demonstrate financial responsibility for an UST system; and failed to submit evidence of financial assurance to the Department upon request.

Action: The Individual/Entity is required to submit: line leak detector function check test results for the 10,000-gallon regular UST (Tank #2); line tightness test results for the 10,000-gallon regular UST (Tank #1); current passing automatic tank gauge record for all USTs at the Facility; proof the overfill prevention equipment for all USTs have been repaired and/or replaced and subsequent overfill prevention equipment operability test results for all UST overfill devices; proof a Class A/B Operator/Walkthrough Inspection log is being properly maintained; and a completed Certificate of Financial Responsibility form and evidence of financial assurance by May 21, 2022. The Department has assessed a total civil penalty in the amount of eighteen thousand, nine hundred thirty-five dollars

(\$18,935.00). The Individual/Entity shall pay a civil penalty in the amount of eighteen thousand, nine hundred thirty-five dollars (**\$18,935.00**) by May 21, 2022.

Updates: No Request for Review was filed; therefore, the effective date of the Order is April 7, 2022. Rec'd Financial Responsibility documentation. The Order will be referred to Office of General Counsel for further action.

3) Order Type and Number: Administrative Order 21-0021-UST
 Order Date: March 31, 2022
 Individual/Entity: **Terratec, Inc.**
 Facility: Terratec. Inc.
 Location: 1350 Methodist Park Road
 West Columbia, SC 29170

 Mailing Address: Same
 County: Lexington
 Previous Orders: None
 Permit/ID Number: 06089
 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, 243.65(a) (2012 & Supp 2020).

Summary: Terratec, Inc. (Individual/Entity) owns an underground storage tank in Lexington County, South Carolina. On November 24, 2020, the Department conducted a routine inspection and issued a Notice of Alleged Violation. The Individual/Entity violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to provide proof the Class A/B operator designated for the Facility completed Class A/B operator supplemental training by May 26, 2020.

Action: The Individual/Entity is required to: submit certification that the Class A/B operator designated for the Facility has completed the Class A/B operator supplemental. The Department has assessed a civil penalty in the amount of one thousand, five hundred dollars (\$1,500.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, five hundred dollars (**\$1,500.00**) by May 30, 2022.

Update: No Request for Review was filed; therefore, the effective date of the Order is April 16, 2022.

4) Order Type and Number: Administrative Order 21-0494-UST
 Order Date: April 6, 2022
 Individual/Entity: **Property Management VDDAB, Ltd.**
 Facility: Corner Stop 43 SC 671
 Location: 3852 Byrnes Drive
 St. Stephen, SC 29479

 Mailing Address: 2216 India Hook Road
 Rock Hill, SC 29732

 County: Berkeley
 Previous Orders: None
 Permit/ID Number: 01213
 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, 280.31(a), 280.70(c), 280.93(a), and 280.110(c) (2012 and Supp. 2020).

Summary: Property Management VDDAB, Ltd. (Individual/Entity) owns and operates underground storage tanks (USTs) in Berkeley County, South Carolina. On May 19 and July 30, 2021, the Department conducted a file review and issued a Notice of Alleged Violation (NOAV). The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to operate and maintain corrosion protection equipment continuously; 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; failed to submit evidence of financial assurance to the Department upon request; and failed to pay annual tank registration fees (ATRFs).

Action: The Individual/Entity is required to: submit a completed Certificate of Financial Responsibility form and evidence of financial assurance; pay ATRFs in the amount of four hundred eighty-four dollars (\$484.00); submit a completed Tank and Sludge Disposal form for the permanent closure of the USTs at the Facility; and within sixty (60) days after the USTs have been permanently closed, submit a Closure and Assessment report by June 6, 2022. The Department has assessed a total civil penalty in the amount of thirty-two thousand, two hundred dollars (\$32,200.00). The Individual/Entity shall pay a civil penalty in the amount of thirty-two thousand, two hundred dollars (**\$32,200.00**) by June 6, 2022.

Update: No Request for Review was filed; therefore, the effective date of the Order is April 23, 2022. The Individual/Entity filed bankruptcy and has been dissolved. The Order is closed, and the matter referred back to the UST Program.

5) Order Type and Number: Consent Order 21-0562-UST
 Order Date: April 6, 2022
 Individual/Entity: **Hardwick Patel**
 Facility: Price Shell
 Location: 1556 Whiskey Road
 Aiken, SC 29801
 Mailing Address: 273 Equinox Loop
 Aiken, SC 29803
 County: Aiken
 Previous Orders: None
 Permit/ID Number: 12895
 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, 280.26(f) (2012 & Supp 2020).

Summary: Hardwick Patel (Individual/Entity) owns underground storage tanks in Aiken County, South Carolina. On October 1, 2021, the Department conducted an inspection and issued a Notice of Alleged Violation. The Individual/Entity violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: received an illegal delivery while tank(s) were under delivery prohibition.

Action: The Individual/Entity has corrected the violations. The Department has assessed a civil penalty in the amount of five thousand dollars (\$5,000.00). The Individual/Entity is required to pay a civil penalty in the amount of five thousand dollars (**\$5,000.00**) by May 21, 2022.

Update: The civil penalty has been paid in full. The Order is closed.

6) Order Type and Number: Consent Order 22-0001-UST
Order Date: April 6, 2022
Individual/Entity: **7 Swami, LLC**
Facility: Lynchburg Grocery
Location: 20 East Willow Grove Road
Lynchburg, SC 29080
Mailing Address: 3201 Strada Angelo
Florence, SC 29501
County: Lee
Previous Orders: None
Permit/ID Number: 17439
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, 280.20(c)(1)(ii) (2012 & Supp 2020).

Summary: 7 Swami, LLC (Individual/Entity) owns underground storage tanks in Lee County, South Carolina. On October 1, 2021, the Department conducted an inspection and issued a Notice of Alleged Violation. The Individual/Entity violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to maintain overfill prevention equipment by having an obstruction in the drop tube.

Action: The Individual/Entity has corrected the violation. The Department has assessed a total civil penalty in the amount of six thousand dollars (\$6,000.00). The Individual/Entity shall pay a civil penalty in the amount of six thousand dollars (**\$6,000.00**) in accordance with a promissory note beginning April 20, 2022.

Update: Monthly payments are being made as required towards the civil penalty.

7) Order Type and Number: Consent Order 22-0024-UST
Order Date: April 6, 2022
Individual/Entity: **Browns Ferry, LLC**
Facility: 51 Express
Location: 7359 Browns Ferry Road
Georgetown, SC 29440
Mailing Address: 1920 West Lucas Street
Florence, SC 29501
County: Georgetown
Previous Orders: None
Permit/ID Number: 12199
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, 280.20(c)(1)(ii) (2012 and Supp. 2020).

Summary: Browns Ferry, LLC (Individual/Entity) owns and operates underground storage tanks (USTs) in Georgetown County, South Carolina. On January 11, 2022, the Department conducted an inspection and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to maintain overfill prevention equipment of an UST system.

Action: The Individual/Entity has corrected the violation. The Department has assessed a total civil penalty in the amount of six thousand dollars (\$6,000.00). The Individual/Entity shall pay a civil penalty in the amount of six thousand dollars (**\$6,000.00**) by May 20, 2022.

Update: This Order will be referred to Office of General Counsel for further action.

8) Order Type and Number: Consent Order 22-0085-UST
Order Date: April 21, 2022
Individual/Entity: **Spinx Company, LLC**
Facility: Spinx 133
Location: 2206 North Main Street
Anderson, SC 29621
Mailing Address: P.O. Box 8624
Greenville, SC 29604
County: Anderson
Previous Orders: None
Permit/ID Number: 00559
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, 280.26(f) (2012 & Supp 2020).

Summary: Spinx Company, LLC (Individual/Entity) operates underground storage tanks (USTs) in Anderson County, South Carolina. On February 24, 2022, the Department conducted an inspection and issued a Notice of Alleged Violation. The Individual/Entity violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to maintain overfill prevention equipment.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total penalty in the amount of six thousand dollars (\$6,000.00). The Individual/Entity shall pay a total civil penalty in the amount of six thousand dollars (**\$6,000.00**) by June 6, 2022.

Update: The civil penalty has not been paid and a demand letter was sent June 8, 2022.

9) Order Type and Number: Consent Order 22-0097-UST
Order Date: April 21, 2022
Individual/Entity: **Rock Tank, Inc.**
Facility: Corner Stop 53

Location: 700 Fleming Street
Laurens, SC 29360
Mailing Address: 102 South Broad Street
Clinton, SC 29325
County: Laurens
Previous Orders: None
Permit/ID Number: 11062
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, 280.20(c)(1)(ii) (2012 & Supp 2020).

Summary: Rock Tank, Inc. (Individual/Entity) operates underground storage tanks (USTs) in Laurens County, South Carolina. On March 23, 2022, the Department conducted an inspection and issued a Notice of Alleged Violation. The Individual/Entity violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to maintain overfill prevention equipment.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total penalty in the amount of six thousand dollars (\$6,000.00). The Individual/Entity shall pay a total civil penalty in the amount of six thousand dollars (**\$6,000.00**) by June 6, 2022.

Update: Civil penalty has been paid in full. The Order is closed.

10) Order Type and Number: Consent Order 22-0081-UST
Order Date: May 3, 2022
Individual/Entity: **Padi Reddy**
Facility: South Main Express
Location: 400 South Main Street
Lancaster, SC 29720
Mailing Address: 31 Wildeoak Court
Columbia, SC 29223
County: Lancaster
Previous Orders: None.
Permit/ID Number: 05547
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., 280.93 and 280.110(c), (2012 & Supp 2019).

Summary: Padi Reddy (Individual/Entity) owns underground storage tanks in Lancaster County, South Carolina. On January 18, 2022, the Department conducted a file review and issued an NOAV. The Individual/Entity 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 financial assurance to the Department upon request.

Action: The Individual/Entity is required to: submit a completed Certificate of Financial Responsibility Form and evidence of financial assurance by June 17, 2022. The Department has assessed a total civil penalty in the amount of eight hundred seventy dollars

(\$870.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred seventy dollars (**\$870.00**).

Update: All requirements of the Order have been met and the civil penalty payment penalty paid in full. The Order is closed.

11) Order Type and Number: Consent Order 22-0059-UST
Order Date: May 5, 2022
Individual/Entity: **MDC Coast 11, LLC**
Facility: 7-Eleven 40375
Location: 1515 Highway 17 North
Mt. Pleasant, SC 29464-3308
Mailing Address: 11995 El Camino Real
San Diego, CA 92130
County: Charleston
Previous Orders: None
Permit/ID Number: 01362
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, 280.20(c)1(ii) (2012 & Supp 2020).

Summary: MDC Coast 11, LLC (Individual/Entity) operates underground storage tanks (USTs) in Charleston County, South Carolina. On February 16, 2022, the Department conducted an inspection and issued a Notice of Alleged Violation. The Individual/Entity violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to maintain overfill prevention equipment.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total penalty in the amount of six thousand dollars (\$6,000.00). The Individual/Entity shall pay a civil penalty in the amount of six thousand dollars (**\$6,000.00**) by June 18, 2022.

Update: None.

12) Order Type and Number: Consent Order 22-0096-UST
Order Date: May 11, 2022
Individual/Entity: **Sai Ram SC, LLC**
Facility: EZ Trip 3
Location: 4623 Savannah Highway
North, SC 29169
Mailing Address: 114 McSwain Drive
Columbia, SC 29169
County: Orangeburg
Previous Orders: None
Permit/ID Number: 10631
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, 280.20(c)(1)(ii) (2012 and Supp. 2020).

Summary: Sai Ram SC, LLC (Individual/Entity) owns and operates underground storage tanks (USTs) in Orangeburg County, South Carolina. On March 22, 2022, the Department conducted an inspection and issued a Notice of Alleged Violation (NOAV). The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to maintain overfill prevention equipment of an underground storage tank (UST).

Action: The Individual/Entity is required to: submit proof an overfill prevention equipment device has been installed for Tank #1 and submit subsequent passing overfill prevention equipment operability test results for Tank #1. The Department has assessed a total civil penalty in the amount of six thousand dollars (\$6,000.00). The Individual/Entity shall pay a civil penalty in the amount of six thousand dollars (**\$6,000.00**) by June 25, 2022.

Update: None.

13) Order Type and Number: Consent Order 22-0114-UST
Order Date: May 13, 2022
Individual/Entity: **Jared Wilson d.b.a. Wilson's Corner Store**
Facility: Wilson's Corner Store
Location: 9390 Highway 9
Inman, SC 29349
Mailing Address: Same
County: Spartanburg
Previous Orders: None.
Permit/ID Number: 08655
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, 280.20(c)(1)(ii) (2012 & Supp 2020).

Summary: Jared Wilson d.b.a. Wilson's Corner Store (Individual/Entity) operates underground storage tanks (USTs) in Spartanburg County, South Carolina. On April 6, 2022, the Department conducted an inspection and issued a Notice of Alleged Violation. The Individual/Entity violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to maintain overfill prevention equipment.

Action: The Individual/Entity corrected all violations prior to issuance of the Order. The Department has assessed a total penalty in the amount of six thousand dollars (\$6,000.00). The Individual/Entity shall pay a total civil penalty in the amount of six thousand dollars (**\$6,000.00**) in accordance with a promissory note. The first promissory note payment will be due on May 16, 2022, and the final payment will be due on April 16, 2023.

Update: The first installment on the promissory note has been made.

14) Order Type and Number: Consent Order 22-0102-UST
Order Date: May 14, 2022
Individual/Entity: **Eddie Defee**
Facility: Bulk Plant

Location: 1800 Trade Street
Florence, SC 29503
Mailing Address: 7714 Francis Marion Road
Effingham, SC 29541
County: Florence
Previous Orders: None
Permit/ID Number: 03427
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, 280.70(a) (2012 and Supp. 2020).

Summary: Eddie Defee (Individual/Entity) owns and operates underground storage tanks (USTs) in Florence County, South Carolina. On February 8, 2022, the Department conducted an inspection and issued a Notice of Alleged Violation (NOAV). The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to maintain corrosion protection or appropriate release detection on a temporarily closed UST.

Action: The Individual/Entity has corrected the violation. The Department has assessed a total civil penalty in the amount of four hundred dollars (\$400.00). The Individual/Entity shall pay a total civil penalty in the amount of four hundred dollars (**\$400.00**).

Update: The Individual/Entity paid the assessed civil penalty. The Order is closed.

15) Order Type and Number: Consent Order 22-0112-UST
Order Date: May 27, 2022
Individual/Entity: **Shree Sai, LLC**
Facility: GS Mini Mart
Location: 668 Main Street
West Columbia, SC 29170
Mailing Address: 7103 Nursery Road
Columbia, SC 29212
County: Lexington
Previous Orders: None
Permit/ID Number: 11789
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, 280.20(c)(1)(ii) (2012 and Supp. 2020).

Summary: Shree Sai, LLC (Individual/Entity) owns and operates underground storage tanks (USTs) in Lexington County, South Carolina. On April 5, 2022, the Department conducted an inspection and issued a Notice of Alleged Violation (NOAV). The Individual/Entity has violated the SUPERB Act and South Carolina Underground Storage Tank Control Regulation as follows: failed to maintain overfill prevention equipment of an UST system.

Action: The Individual/Entity has corrected the violation. The Department has assessed a total civil penalty in the amount of six thousand dollars (\$6,000.00). The

Individual/Entity shall pay a civil penalty in the amount of six thousand dollars (**\$6,000.00**) by July 11, 2022.

Update: None.

- 16) Order Type and Number: Consent Order 22-0119-UST
Order Date: May 31, 2022
Individual/Entity: **Thomas E. Ragan**
Facility: Short Stop Food Mart
Location: 7221 Highway 9
Inman, SC 29349
Mailing Address: Same
County: Spartanburg
Previous Orders: None
Permit/ID Number: 08307
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, 280.20(c)(1)(ii) (2012 & Supp 2020).

Summary: Thomas E. Ragan (Individual/Entity) operates underground storage tanks (USTs) in Spartanburg County, South Carolina. On April 15, 2022, the Department conducted an inspection and issued a Notice of Alleged Violation. The Individual/Entity violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to maintain overfill prevention equipment.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total penalty in the amount of six thousand dollars (\$6,000.00). The Individual/Entity shall pay a total civil penalty in the amount of six thousand dollars (**\$6,000.00**) by July 15, 2022.

Update: None.

Solid Waste Enforcement

- 17) Order Type and Number: Administrative Order 22-06-SW
Order Date: April 7, 2022
Individual/Entity: **Ladson Wood Recycling, LLC**
Facility: Ladson Wood Recycling
Location: 9425 Highway 78
Ladson, SC 29456
Mailing Address: Same
County: Charleston
Previous Orders: 19-10-SW (\$8,000.00);
17-32-SW (\$9,000.00)
Permit/ID Number: 102745-3001
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: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings and Organic Residuals Regulation (Rev. 2008 &

Supp. 2016), Part III.E.1.d., Part III.E.1.e., Part III.E.5.c., Part III.E.6., Part III.F.1.d., and Part III.F.5., Solid Waste Management: Used Oil Regulation (2012 & Supp. 2019) 279.12.g., 279.22.b., 279.22.c., and 279.22.d., and the Permit # 102745-3001, Section A.4.

Summary: Ladson Wood Recycling, LLC (Individual/Entity), operates a wood chipping facility located in Charleston County, South Carolina. On February 10, 2022, the Department issued a Notice of Alleged Violation based on routine inspections of the facility. The Individual/Entity has violated the South Carolina Solid Waste Policy and Management Act, the Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings and Organic Residuals Regulation, the Solid Waste Management: Used Oil Regulation, and the Permit in that the Individual/Entity: exceeded the permitted 10,000 cubic yards of unprocessed material; accepted unprocessed material resulting in an excess of the maximum capacity allowed by the Permit; failed to provide temperature logs to the Department upon request; failed to operate the Facility within the permitted boundary; failed to prevent standing water on the operational area; and failed to store used oil in containers that were in good condition, i.e. not leaking, closed, and labeled

Action: The Individual/Entity is required to: immediately cease accepting new, unprocessed material at the facility; reduce the amount of unprocessed material present at the facility to within the permitted limit of 10,000 cubic yards; remove all unprocessed material from outside the facility's permitted footprint, specifically, remove the debris from under the power lines to the west of the facility; close and label all used oil containers; and clean up all used oil spilled in the soil surrounding the used oil containment area by digging out at least six (6) inches of soil in the area where the spills have occurred or until clean soil is observed, whichever is greater by June 8, 2022. The Department has assessed a civil penalty of twenty-one thousand, three hundred dollars (\$21,300.00). The Individual/Entity shall pay a civil penalty of twenty-one thousand, three hundred dollars (**\$21,300.00**) by June 8, 2022.

Update: No Request for Review was filed; therefore, the effective date of the Order is April 25, 2022. This has been referred to Office of General Counsel for further action.

18) Order Type and Number: Consent Order 22-08-SW
Order Date: May 13, 2022
Individual/Entity: **Chester County**
Facility: Chester County Transfer Station
Location: 2351 Penden Bridge Road
Chester, South Carolina 29706
Mailing Address: P.O. Drawer 580
Chester, SC 29706
County: Chester
Previous Orders: None
Permit/ID Number: 121001-6001
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: Transfer of Solid Waste Regulation, C.2. and F.3.(2012); and the Permit #121001-6001, Preliminary Engineering Report and The General Operating Plan.

Summary: Chester County (Individual/Entity), operates a Transfer Station located in Chester County, South Carolina. Based on routine inspections of the Facility, the

Department issued a Notice of Alleged Violations. The Individual/Entity has violated the South Carolina Solid Waste Policy and Management Act, the Solid Waste Management: Transfer of Solid Waste Regulation, and the Permit, as follows: failed to manage leachate at the Facility in accordance with the approved Operating Plan.

Action: The Individual/Entity has corrected all violations. The Department has assessed a civil penalty in the amount of two thousand, five hundred eighty dollars (\$2,580.00). The Individual/Entity shall pay a civil penalty of two thousand, five hundred eighty dollars (**\$2,580.00**) by June 27, 2022.

Update: The civil penalty has been paid in full. The Order is closed.

Hazardous Waste Enforcement

19) Order Type and Number: Consent Order 22-07-HW
Order Date: April 21, 2022
Individual/Entity: **HI-TEC Plating, Inc.**
Facility: HI-TEC Plating, Inc.
Location: 219 Hitec Road
Seneca, SC 29678
Mailing Address: P.O. Box 68
Seneca, SC 29679
County: Oconee
Previous Orders: None
Permit/ID Number: SCD 981 759 343
Violations Cited: The South Carolina Hazardous Waste Management Act, S.C. Code Ann. §§ 44-56-10 et seq. (2018), and the South Carolina Hazardous Waste Management Regulation, 6 and 7 S.C. Code Ann. Regs. 61-79 (2012 and Supp. 2020).

Summary: HI-TEC Plating, Inc. (Individual/Entity) is a metal finisher providing precision electroless nickel plating and hard chrome plating at its facility located in Oconee County, South Carolina. The Department conducted an inspection at the facility on October 27, 2021. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act and the Hazardous Waste Management Regulations as follows: failed to transfer hazardous waste from a container in poor condition to a container in good condition; failed to mark or label containers with the words “Hazardous Waste” and an indication of the hazards of the contents; failed to submit a copy of the contingency plan and the quick reference guide to all the local emergency responders; failed to label universal waste lamps with one of the following phrases: “Universal Waste Lamp(s),” or “Waste Lamp(s),” or “Used Lamp(s);” and failed to demonstrate the length of time universal waste had been accumulated.

Action: The Individual/Entity has corrected the violations. The Department has assessed a total civil penalty in the amount of four thousand dollars (\$4,000.00). The Individual/Entity is required to pay a civil penalty in the amount of four thousand dollars (**\$4,000.00**) by May 23, 2022.

Update: The civil penalty was paid in full on May 11, 2022. The Order is closed.

20) Order Type and Number: Consent Order 22-08-HW
Order Date: May 11, 2022
Individual/Entity: **AkzoNobel Coatings, Inc.**
Facility: AkzoNobel Coatings, Inc.
Location: 1872 Highway 9 Bypass West
Lancaster, SC 29720
Mailing Address: Same
County: Lancaster
Previous Orders: None
Permit/ID Number: SCD 000 608 331
Violations Cited: The South Carolina Hazardous Waste Management Act, S.C. Code Ann. §§ 44-56-10 et seq. (2018), and the South Carolina Hazardous Waste Management Regulation, 6 and 7 S.C. Code Ann. Regs. 61-79 (2012 and Supp. 2021).

Summary: AkzoNobel Coatings, Inc. (Individual/Entity) is a global paint and coating company that produces decorative paints and specialty coatings at its facility located in Lancaster County, South Carolina. The Department conducted an inspection at the facility on January 13, 2022. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act and the Hazardous Waste Management Regulations as follows: failed to accumulate hazardous waste in containers at or near any point of generation; failed to mark or label containers with the words “Hazardous Waste” and an indication of the hazards of the contents; failed to remove excess hazardous waste from satellite accumulation within three (3) consecutive calendar days and date the container holding the excess with the date the excess amount began accumulating; failed to place “No Smoking” signs in areas where ignitable or reactive waste was stored; failed to have a training program directed by a person trained in hazardous waste management; failed to ensure personnel take part in an annual review of hazardous waste training; failed to maintain the job title for each position related to hazardous waste management at the facility and the name of the employee filling that position; failed to maintain a written job description for each position; failed to maintain a written description of the type and amount of both introductory and continuing training given to each person; failed to prepare hazardous waste manifests according to the instructions; failed to submit Quarterly Reports to the Department that included a description, the EPA hazardous waste number, DOT hazardous class, and the types and quantities of such wastes as required by the instructions included with the form; failed to describe and/or include in the facility’s Contingency Plan, the arrangements agreed to with local emergency responders and a list of all emergency equipment along with the location and its capabilities; failed to submit a copy of the contingency plan along with a quick reference guide to all local emergency responders; failed to label containers of universal waste lamps and contain any lamps in a manner to prevent a release and to keep such containers closed; and failed to demonstrate the length of time universal waste had been accumulated from the date it became a waste.

Action: The Individual/Entity has corrected the violations. The Department has assessed a total civil penalty in the amount of seventeen thousand dollars (\$17,000.00). The Individual/Entity is required to pay a civil penalty in the amount of seventeen thousand dollars (**\$17,000.00**) by July 11, 2022.

Update: None

Infectious Waste Enforcement

- 21) Order Type and Number: Consent Order 22-09-IW
Order Date: April 11, 2022
Individual/Entity: **Ashley River Tower**
Facility: Ashley River Tower
Location: 25 Courtenay Drive
Charleston, SC 29425
Mailing Address: 316 Courtenay Drive
Charleston, SC 29425
County: Charleston
Previous Orders: 20-01-IW (\$14,800.00)
Permit/ID Number: SC10-2208G
Violations Cited: The South Carolina Infectious Waste Management Act, S.C. Code ann. §§ 44-93-10 et seq. (2002); and the South Carolina Infectious Waste Management Regulation, 8. S.C. Code Ann. Regs. 61-105 (2010).

Summary: Ashley River Tower (Individual/Entity), under the healthcare system of the Medical University of South Carolina specializes in digestive health, heart and vascular care, and cancer care at its facility located in Charleston County, South Carolina. On September 14, 2021, the Department opened an investigation and conducted site visits on September 16, 2021, September 24, 2021, September 28, 2021, October 13, 2021, and October 21, 2021. The Individual/Entity has violated the South Carolina Infectious Waste Management Act and the South Carolina Infectious Waste Management Regulation as follows: failed to segregate infectious waste at the point of generation; failed to manage infectious waste in a manner which prevents exposure to the public or release to the environment; failed to offer infectious waste for offsite transport only to a transporter registered with the Department or the U.S. Postal Service; failed to package infectious waste in accordance with the requirements of R.61-105 Section I to prevent a release; failed to place and maintain all sharps in a rigid, leak-resistant, and puncture resistant containers; failed to place, store, and maintain all other types of infectious waste during transport in rigid or semirigid leak-resistant containers; failed to use containers that had sufficient strength to prevent bursting and tearing; failed to use plastic bags that were red or orange color and had sufficient strength to prevent tearing; failed to contain infectious waste in containers that were appropriate for storage, transportation, and treatment processes; failed to label containers of infectious waste with the universal biohazard symbol, the Department issued number of the in-state generator, and the date the container was placed in storage or sent offsite; failed to treat infectious waste prior to disposal; and failed to report to the Department within twenty-four (24) hours and investigate and confirm all suspected releases of infectious waste.

Action: The Individual/Entity has corrected the violations. The Department has assessed a total civil penalty in the amount of fifty-eight thousand dollars (\$58,000.00). The Individual/Entity shall pay a civil penalty of fifty-eight thousand dollars (**\$58,000.00**) by May 11, 2022.

Update: Civil penalty has been paid in full. The Order is closed.

- 22) Order Type and Number: Consent Order 22-10-IW
Order Date: April 11, 2022

Individual/Entity: **Medical University of South Carolina**
Facility: Medical University of South Carolina
Location: 171 Ashley Avenue
Charleston, South Carolina 29425
Mailing Address: Same
County: Charleston
Previous Orders: 20-02-IW (\$14,800.00)
Permit/ID Number: SC10-0031G
Violations Cited: The South Carolina Infectious Waste Management Act, S.C. Code ann. §§ 44-93-10 et seq. (2002); and the South Carolina Infectious Waste Management Regulation, 8. S.C. Code Ann. Regs. 61-105 (2010).

Summary: The Medical University of South Carolina (Individual/Entity), is a clinical healthcare system centrally located in Charleston County, South Carolina. On September 14, 2021, the Department opened an investigation and conducted site visits on September 16, 2021, September 24, 2021, September 28, 2021, October 13, 2021, and October 21, 2021. The Individual/Entity has violated the South Carolina Infectious Waste Management Act and the South Carolina Infectious Waste Management Regulation as follows: failed to segregate infectious waste at the point of generation; failed to manage infectious waste in a manner which prevents exposure to the public or release to the environment; failed to offer infectious waste for offsite transport only to a transporter registered with the Department or the U.S. Postal Service; failed to package infectious waste in accordance with the requirements of R.61-105 Section I to prevent a release; failed to place and maintain all sharps in a rigid, leak-resistant, and puncture resistant containers; failed to place, store, and maintain all other types of infectious waste during transport in rigid or semirigid leak-resistant containers; failed to use containers that had sufficient strength to prevent bursting and tearing; failed to use plastic bags that were red or orange color and had sufficient strength to prevent tearing; failed to contain infectious waste in containers that were appropriate for storage, transportation, and treatment processes; failed to label containers of infectious waste with the universal biohazard symbol, the Department issued number of the in-state generator, and the date the container was placed in storage or sent offsite; failed to treat infectious waste prior to disposal; and failed to report to the Department within twenty-four (24) hours and investigate and confirm all suspected releases of infectious waste.

Action: The Individual/Entity has corrected the violations. The Department has assessed a total civil penalty in the amount of fifty-eight thousand dollars (\$58,000.00). The Individual/Entity shall pay a civil penalty of fifty-eight thousand dollars (**\$58,000.00**) by May 11, 2022.

Update: The civil penalty has been paid in full. The Order is closed.

23) Order Type and Number: Consent Order 22-15-IW
Order Date: May 5, 2022
Individual/Entity: **Trident Medical Center**
Facility: Trident Medical Center
Location: 9330 Medical Plaza Drive
North Charleston, SC 29406
Mailing Address: Same
County: Charleston
Previous Orders: None

Permit/ID Number: SC10-0258G
Violations Cited: The South Carolina Infectious Waste Management Act, S.C. Code ann. §§ 44-93-10 et seq. (2002); and the South Carolina Infectious Waste Management Regulation, 8. S.C. Code Ann. Regs. 61-105 (2010).

Summary: Trident Medical Center (Individual/Entity), is a clinical healthcare system centrally located in Charleston County, South Carolina. On October 8, 2021, the Department opened an investigation and conducted site visits on October 8, 2021, October 13, 2021, October 15, 2021, October 20, 2021, October 25, 2021, October 29, 2021, November 2, 2021, November 5, 2021, and December 15, 2021. The Individual/Entity has violated the South Carolina Infectious Waste Management Act and the South Carolina Infectious Waste Management Regulation as follows: failed to segregate infectious waste at the point of generation; failed to manage infectious waste in a manner which prevents exposure to the public or release to the environment; failed to offer infectious waste for offsite transport only to a transporter registered with the Department or the U.S. Postal Service; failed to package infectious waste in accordance with the requirements of R.61-105 Section I to prevent a release; failed to place and maintain all sharps in a rigid, leak-resistant, and puncture resistant containers; failed to place, store, and maintain all other types of infectious waste during transport in rigid or semirigid leak-resistant containers; failed to use containers that had sufficient strength to prevent bursting and tearing; failed to use plastic bags that were red or orange color and had sufficient strength to prevent tearing; failed to contain infectious waste in containers that were appropriate for storage, transportation, and treatment processes; failed to label containers of infectious waste with the universal biohazard symbol, the Department issued number of the in-state generator, and the date the container was placed in storage or sent offsite; failed to treat infectious waste prior to disposal; and failed to report to the Department within twenty-four (24) hours and investigate and confirm all suspected releases of infectious waste.

Action: The Individual/Entity has corrected the violations. The Department has assessed a total civil penalty in the amount of fifty-five thousand, three hundred dollars (\$55,300.00). The Individual/Entity shall pay a civil penalty of fifty-five thousand, three hundred dollars (**\$55,300.00**) by June 5, 2022.

Update: The civil penalty was paid in full on May 11, 2022. The Order is closed.

24) Order Type and Number: Consent Order 22-11-IW
Order Date: May 17, 2022
Individual/Entity: **Naval Health Clinic Charleston**
Facility: Naval Health Clinic Charleston
Location: 110 Naval Nuclear Power Training Command Circle
Goose Creek, SC 29445
Mailing Address: Same
County: Berkeley
Previous Orders: None
Permit/ID Number: SC08-0187G
Violations Cited: The South Carolina Infectious Waste Management Act, S.C. Code ann. §§ 44-93-10 et seq. (2002); and the South Carolina Infectious Waste Management Regulation, 8. S.C. Code Ann. Regs. 61-105 (2010).

Summary: Naval Health Clinic Charleston (Individual/Entity), operates a Military Health System hospital located in Berkeley County, South Carolina. The Department conducted an open investigation on November 3, 2021. The Individual/Entity has violated the South Carolina Infectious Waste Management Act and the South Carolina Infectious Waste Management Regulation as follows: failed to segregate infectious waste at the point of generation; failed to properly manage infectious waste; failed to offer infectious waste for offsite transport only to a registered transporter; failed to package infectious waste in accordance with the regulations; failed to place, store, and maintain all other types of infectious waste during transport in rigid or semirigid leak-resistant containers; failed to contain infectious waste in containers that were appropriate for storage, transportation, and treatment processes; failed to properly label containers of infectious waste; failed to treat infectious waste prior to disposal; and failed to report to the Department within twenty-four (24) hours and investigate and confirm all suspected releases of infectious waste.

Action: The Individual/Entity has corrected the violations. The Department has assessed a total civil penalty in the amount of fourteen thousand, four hundred dollars (\$14,400.00). The Individual/Entity shall pay a civil penalty of fourteen thousand, four hundred dollars (**\$14,400.00**) by June 16, 2022.

Update: The civil penalty has been paid in full. The Order is closed.

Mining Enforcement

25) Order Type and Number: Consent Order 22-03-MSWM
Order Date: May 27, 2022
Individual/Entity: **S&T Recycling, LLC**
Facility: S&T Recycling Mine
Location: approximately 2.5 miles northeast of Lexington, South Carolina, adjacent to US Highway 378 and 2.75 miles west of its intersection with Interstate 20
Mailing Address: 5009 Sunset Boulevard
Lexington, SC 29072
County: Lexington
Previous Orders: None
Permit/ID Number: I-001584
Violations Cited: The South Carolina Mining Act, S.C. code Ann. § 48-20-10 et seq. (2008 & Supp. 2018); South Carolina Mining Regulation (2012) R.89-280; and the Permit I-002002 Section IX.1.

Summary: S&T Recycling, LLC (Individual/Entity), owns and operates S&T Recycling Mine in Lexington County, South Carolina. The Department conducted a file review on December 6, 2021. The Individual/Entity has violated the South Carolina Mining Act, the Mining Regulation, and the Permit as follows: failed to submit the mining annual report for fiscal year 2022.

Action: The Individual/Entity is required to: submit the mining annual report for fiscal year 2022 by July 11, 2022. The Department has assessed a civil penalty in the amount six hundred dollars (\$600.00). The Individual/Entity shall pay a civil penalty of six hundred dollars (**\$600.00**) by July 11, 2022.

Update: All requirements of the Order have been met. The Order is closed.

BUREAU OF WATER

Recreational Waters Enforcement

26) Order Type and Number: Consent Order 22-013-RW
Order Date: May 17, 2022
Individual/Entity: **Ocean Breeze Hospitality, LLC**
Facility: Sleep Inn at Harbour View
Location: 909 Highway 17
Little River, SC 29566
Mailing Address: Same
County: Horry
Previous Orders: None
Permit/ID Number: 26-P47-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Ocean Breeze Hospitality, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Horry County, South Carolina. The Department conducted inspections on January 12, 2022, and April 5, 2022, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: skimmers were missing weirs; the chlorine level was not within the acceptable range of water quality standards; the facility address was not posted at the emergency notification device; and the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of six hundred eighty dollars (\$680.00). The Individual/Entity shall pay a civil penalty in the amount of six hundred eighty dollars (**\$680.00**) by June 6, 2022.

Update: The civil penalty has been paid and the Order has been closed.

27) Order Type and Number: Consent Order 22-014-RW
Order Date: May 24, 2022
Individual/Entity: **University of South Carolina**
Facility: Strom Thurmond Wellness and Fitness Center
Location: 1000 Blossom Street
Columbia, SC 29201
Mailing Address: Same
County: Richland
Previous Orders: None
Permit/ID Number: 40-430-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)(10)

Summary: The University of South Carolina (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department issued a Notice of Alleged Violation/Notice of Enforcement Conference on April 18, 2022, as a result of a review of Department records. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: failed to report to the Department in writing, on a Department approved form, any death, injury, or accident requiring an EMS response, emergency room visit, or hospitalization within seventy-two hours of the occurrence.

Action: The Department has assessed a total civil penalty in the amount of four hundred dollars (\$400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars (**\$400.00**) by June 8, 2022.

Update: The civil penalty has been paid. The Individual/Entity submitted the required incident report to the Department. The Order has been closed.

Drinking Water Enforcement

28) <u>Order Type and Number:</u>	Consent Order 22-015-DW
<u>Order Date:</u>	April 21, 2022
<u>Individual/Entity:</u>	Tony L. Spires
<u>Facility:</u>	Breakaways on 178
<u>Location:</u>	1032 Highway 178 Pelion, SC 29123
<u>Mailing Address:</u>	Same
<u>County:</u>	Lexington
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	3272010
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-58.7 & 61-58.8.B

Summary: Tony L. Spires (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Lexington County, South Carolina. The Department conducted an inspection on January 28, 2022, and the PWS was rated unsatisfactory for failure to properly operate and maintain and failure to provide an emergency preparedness plan. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: the insulation inside the well house was wet and moldy; the sanitary seal and air vent were covered with a PVC cap and the condition could not be determined; there was exposed wiring that was not in conduit; there was a rope coming out of the wellhead; there was no check valve; there was no blow-off; the wellhead piping rattled when the well pump came on; the sample tap was threaded; the exterior of the storage tank was rusted; a procedures manual with monitoring records, programs, inspection logs, and a system map was not provided for Department review; and an emergency preparedness plan was not provided for Department review.

Action: The Individual/Entity is required to: correct the deficiencies by July 1, 2022; submit a completed procedures manual by July 1, 2022; and submit an emergency preparedness plan by July 1, 2022. The Department has assessed a total civil penalty in the amount of eight thousand dollars (\$8,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of eight thousand dollars (**\$8,000.00**) should any requirement of the Order not be met.

Update: The Individual/Entity has hired a professional well drilling and repair company to correct the deficiencies. The deficiencies have been addressed and the Order has been closed.

29) Order Type and Number: Consent Order 22-016-DW
Order Date: April 21, 2022
Individual/Entity: **Derby Fields Mobile Home Park, LLC**
Facility: Derby Fields Mobile Home Park
Location: 205 Jockey Street
Walterboro, SC 29488
Mailing Address: P.O. Box 2301
Walterboro, SC 29488
County: Colleton
Previous Orders: None
Permit/ID Number: 1560015
Violations Cited: S.C. Code Ann. Regs. 61-58.7, 61-58.8.B, & 61-30.G(2)(a)

Summary: Derby Fields Mobile Home Park, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Colleton County, South Carolina. The Department conducted an inspection on December 7, 2021, and the PWS was rated needs improvement for failure to properly operate and maintain; failure to provide an emergency preparedness plan; and failure to pay the annual Safe Drinking Water Act fee for fiscal year 2022. The Individual/Entity has violated the State Primary Drinking Water Regulation and the Environmental Protection Fees Regulation as follows: the sanitary seal was rusted; the well house was in disrepair and the floor was covered with debris; the well house door was not locked and the door was in disrepair; there was fiberglass insulation covering the wellhead piping; a procedures manual with monitoring records, programs, inspection logs, and a system map was not provided for Department review; an emergency preparedness plan was not provided for Department review; and the annual Safe Drinking Water Act fee for fiscal year 2022 had not been paid.

Action: The Individual/Entity is required to: pay the annual Safe Drinking Water Act fee for fiscal year 2022, which totals two hundred forty dollars and sixty-three cents (**\$240.63**) by April 15, 2022; correct the deficiencies by June 1, 2022; submit a completed procedures manual by June 1, 2022; and submit an emergency preparedness plan by June 1, 2022. The Department has assessed a total civil penalty in the amount of eight thousand dollars (\$8,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of eight thousand dollars (**\$8,000.00**) should any requirement of the Order not be met.

Update: The Individual/Entity has paid the annual Safe Drinking Water Act fee for fiscal year 2022 and hired a professional well drilling and repair company to correct the deficiencies. The deficiencies have been addressed and the Order has been closed.

30) Order Type and Number: Consent Order 22-018-DW
Order Date: April 28, 2022
Individual/Entity: **Draytonville/ Water Works, Inc.**
Facility: Draytonville Water District
Location: 3142 Union Highway
Gaffney, SC 29340

Mailing Address: P.O. Box 1256
Gaffney, SC 29342
County: Cherokee
Previous Orders: 20-001-DW (\$4,000.00)
Permit/ID Number: 1050011
Violations Cited: S.C. Code Ann. Regs. 61-58.5.P(2)(b)

Summary: Draytonville Water Works, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Cherokee County, South Carolina. On March 8, 2022, 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 exceeded the maximum contaminant level (MCL) for total trihalomethanes.

Action: The Individual/Entity is required to: submit a corrective action plan with a schedule to address the MCL violation by May 30, 2022. The Department has assessed a total civil penalty in the amount of eight thousand dollars (\$8,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of eight thousand dollars (**\$8,000.00**) should any requirement of the Order not be met.

Update: The Individual/Entity has received funding to install measures to address the MCL violation. A corrective action plan was submitted and approved.

31) Order Type and Number: Consent Order 22-019-DW
Order Date: May 12, 2022
Individual/Entity: **Georgetown County Water & Sewer District**
Facility: Red Hill
Location: 465 Clearwater Drive
Pawleys Island, SC 29585
Mailing Address: P.O. Box 2730
Pawleys Island, SC 29585
County: Georgetown
Previous Orders: None
Permit/ID Number: 2220007
Violations Cited: S.C. Code Ann. Regs. 61-58.2.B(1)(a) & 61-58.4.C(5)

Summary: Georgetown County Water & Sewer District (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Georgetown County, South Carolina. The Department conducted an inspection of the PWS on November 18, 2021, and it was rated unsatisfactory for source quantity. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: failed to provide a minimum of two independent sources of groundwater; and failed to provide elevated storage.

Action: The Individual/Entity is required to: submit a corrective action plan with a schedule to address the source quantity deficiencies by June 12, 2022. The Department has assessed a total civil penalty in the amount of two thousand dollars (\$2,000.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand dollars (**\$2,000.00**) by June 12, 2022.

Update: The civil penalty has been paid. A corrective action plan was submitted and approved.

32) Order Type and Number: Consent Order 22-020-DW
Order Date: May 27, 2022
Individual/Entity: **Kiser & Associates, Inc.**
Facility: Maryfield Development
Location: 12 Maryfield Court
Daufuskie Island, SC 29915
Mailing Address: P.O. Box 2030
Bluffton, SC 29910
County: Beaufort
Previous Orders: None
Permit/ID Number: 0750045
Violations Cited: S.C. Code Ann. Regs. 61-58.17.K(1), 61-58.7, & 61-58.8.B

Summary: Kiser & Associates, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Beaufort County, South Carolina. On February 8, 2022, a violation was issued as a result of review of monitoring records; and the Department conducted an inspection of the PWS on February 14, 2022, and it was rated unsatisfactory for failure to properly operate and maintain and failure to provide an emergency preparedness plan. 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 for E. coli; the sanitary seal was rusted; the well pad was covered with debris; there was no pressure gauge on the distribution line; there was overgrown vegetation around the well house and storage tank; there were items stored in the well house that were not related to the operation and maintenance of the PWS; the well house was in disrepair; a procedures manual with monitoring records, programs, inspection logs, and a system map was not provided for Department review; and an emergency preparedness plan was not provided for Department review.

Action: The Individual/Entity is required to: submit an investigative report and a corrective action plan with a schedule to address the causes of the total coliform and E. coli present results at the PWS by August 1, 2022; correct the operation and maintenance deficiencies by August 1, 2022; submit an emergency preparedness plan by August 1, 2022; have the storage tank inspected and submit an inspection report with recommendations to the Department by August 1, 2022; and complete the recommendations in the inspection report within ninety days of the date of the report. The Department has assessed a total civil penalty in the amount of twelve thousand dollars (\$12,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of twelve thousand dollars (**\$12,000.00**) should any requirement of the Order not be met.

Update: None.

Water Pollution Enforcement

33) Order Type and Number: Consent Order 22-022-W
Order Date: April 7, 2022

Individual/Entity: **Petrochoice LLC**
Facility: Petrochoice LLC WWTF
Location: 1445 Greenleaf Street
Charleston, SC 29405
Mailing Address: Same
County: Charleston
Previous Orders: 20-009-W
22-004-W
Permit/ID Number: SC0047261
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a)

Summary: Petrochoice LLC (Individual/Entity) is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Charleston County, South Carolina. On October 28, 2021, a Notice of Alleged Violation was issued as a result of violations of the permitted discharge limits for pH as 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 effluent discharge limits of its National Pollutant Discharge Elimination System permit for pH.

Action: The Individual/Entity is required to: submit a written notification of the completion date for all corrective actions necessary to resolve the violations by May 7, 2022; conduct a six (6) event compliance confirmation period upon completion of corrective actions; and implement engineered upgrades to the WWTF should additional violations be observed during the compliance confirmation period. The Department has assessed a total civil penalty in the amount of two thousand, eight hundred dollars (\$2,800.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand, eight hundred dollars **(\$2,800.00)** by May 7, 2022.

Update: The Individual/Entity has submitted notification of the corrective action completion date and payment of the assessed civil penalty. The Order was closed on April 14, 2022.

34) Order Type and Number: Consent Order 22-023-W
Order Date: April 8, 2022
Individual/Entity: **David Martin**
Facility: Martin Dairy Farm
Location: Pendleton, SC 29670
Mailing Address: 104 Martin Lane
Pendleton, SC 29670
County: Anderson
Previous Orders: None
Permit/ID Number: ND0014184
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110 (d) (2008 & Supp. 2019) and Water Pollution Control Permits Regulation, S.C. Code Ann Regs. 61-9.122.41(a) (2011), and ND0014184

Summary: David Martin (Individual/Entity) owns and is responsible for the proper operation and maintenance of Martin Dairy Farm, a dairy farm in Anderson County, South Carolina. On January 11, 2022, a Notice of Alleged Violation (NOAV) was issued as a result of failure to pay past due annual operating fees to the Department for Fiscal Years

2009 through 2021. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulations as follows: failure to remit payment for annual operating fees for Fiscal Years 2009 through 2021.

Action: The Individual/Entity is required to: submit a Close-out Plan developed by a qualified engineer or initiate action initiate with the Natural Resource Conservation Service (NRCS) by June 8, 2022, to close-out the lagoon; and submit in the amount of six hundred and eighteen dollars and seventy-five cents (\$618.75), in settlement of all past due annual operating fees and their associated late fees by June 8, 2022. The Department has assessed a total civil penalty in the amount of four thousand, thirty-six dollars and nine cents (\$4,036.09). The Individual/Entity shall pay a civil penalty in the amount of four thousand, thirty-six dollars and nine cents (**\$4,036.09**) by July 7, 2022.

Update: The Individual/Entity failed to submit the requirements of the Order by the specified due dates. Department staff have attempted to contact the Individual/Entity to facilitate compliance and such attempts have been unsuccessful. A Notice of Order Violation/Demand Letter for Compliance is being prepared for this case.

35) Order Type and Number: Consent Order 22-024-W
Order Date: April 21, 2022
Individual/Entity: **Dominion Energy SC, Inc**
Facility: VC Summer Nuclear Station Off-Site Water System
Location: 400 Brabham Boulevard
Jenkinsville, SC 29065
Mailing Address: P.O. Box 8, Mail Code 800
Jenkinsville, SC 29065
County: Fairfield
Previous Orders: None
Permit/ID Number: SCG646072
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d), Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41(a) and (e)(1), State Environmental Laboratory Certification Regulations, S.C. Code Ann. Regs 61-68 and National Pollutant Discharge Elimination System (NPDES) Permit SC0031895.

Summary: Dominion Energy SC, Inc (Individual/Entity) owns and is responsible for the proper operation and maintenance of the VC Summer Nuclear Station Off-Site Water System (VC Summer WWTF) in Fairfield County, South Carolina. On January 6, 2022, a Notice of Alleged Violation (NOAV) was issued for failure to use a South Carolina certified laboratory for analysis of total residual chlorine (TRC) for certain monitoring periods. The Individual/Entity has violated the Pollution Control Act, Water Pollution Control Permits Regulations, and State Environmental Laboratory Certification Regulations as follows: failed to use South Carolina certified laboratory for analysis of TRC for certain monitoring periods.

Action: The Individual/Entity is required to submit notification by May 6, 2022, that it is using a South Carolina certified laboratory for the analysis of TRC. The Department has assessed a total civil penalty in the amount of eight thousand, one hundred sixty dollars (\$8,160.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand eighty dollars (**\$4,080.00**) by May 21, 2022 and pay a stipulated penalty in

the amount of four thousand eighty dollars (\$4,080.00) should any requirement of the Order not be met.

Update: The Individual/Entity has paid the penalty and submitted documentation confirming proper TRC sampling and analysis. The Order was closed on May 12, 2022.

36) Order Type and Number: Consent Order 22-025-W
Order Date: April 21, 2022
Individual/Entity: **City of Dillon**
Facility: Little Pee Dee WWTF
Location: 1 mile east of city limits and half mile south of state Highway 9
Dillon, SC 29405
Mailing Address: P.O. Box 431
Dillon, SC 29405
County: Dillon
Previous Orders: None
Permit/ID Number: SC0021776
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a)

Summary: The City of Dillon (Individual/Entity) is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Dillon County, South Carolina. On January 27, 2022, a Notice of Alleged Violation was issued as a result of violations of the permitted discharge limits for ammonia-nitrogen (ammonia) as 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 effluent discharge limits of its National Pollutant Discharge Elimination System permit for ammonia.

Action: The Individual/Entity is required to: submit a written notification of the completion date for all corrective actions necessary to resolve the violations by May 21, 2022; conduct a six (6) event compliance confirmation period upon completion of corrective actions; and implement engineered upgrades to the WWTF should additional violations be observed during the compliance confirmation period. The Department has assessed a total civil penalty in the amount of four thousand, nine hundred dollars (\$4,900.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand, nine hundred dollars (**\$4,900.00**) by May 21, 2022.

Update: The Individual/Entity submitted a corrective action plan in response to the Order and has paid the civil penalty. Department staff is in correspondence with the Individual/Entity to assist with the proper notification of corrective action being submitted as required by the Order.

37) Order Type and Number: Consent Order 22-026-W
Order Date: April 27, 2022
Individual/Entity: **Lake Shore Vision, LLC**
Facility: Haigs Creek Subdivision Phase IX
Location: Located off Emory Road
Kershaw County, SC

Mailing Address: P.O. Box 1605
Columbia, SC 29202
County: Kershaw
Previous Orders: None
Permit/ID Number: SCR10Z5PE
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-90 (a); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a) and (e).

Summary: Lake Shore Vision, LLC (Individual/Entity) is responsible for land disturbing activity associated with construction located in Oconee County, South Carolina. On December 16, 2021, notification of unsatisfactory conditions and an inspection report was issued to the Individual/Entity as a result of an unsatisfactory Department inspection of the site. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulations as follows: failed to maintain stormwater management, sediment, and erosion controls per the Department approved plans as required by the Permit.

Action: The Individual/Entity is required to: submit an updated Storm Water Prevention Plan (SWPPP) by June 26, 2022; submit a report signed by a Professional Engineer stating the Site is in compliance with the approved SWPPP and submit a notarized document confirming appropriate inspections are being performed on Site by May 27, 2022; submit a Notice of Termination (NOT) within thirty (30) days of completion of permanent stabilization of the Site. The Department has assessed a total civil penalty in the amount of one thousand, fifty dollars (\$1,050.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, fifty dollars (**\$1,050.00**) due May 27, 2022.

Update: The Individual/Entity has submitted payment of the penalty and has submitted an updated SWPPP for Department approval

38) Order Type and Number: Consent Order 22-027-W
Order Date: May 5, 2022
Individual/Entity: **Centerfield Cooper Solar, LLC**
Facility: Centerfield Cooper Solar site
Location: Chesterfield, SC 29709
Mailing Address: 130 Roberts Street, Suite 120
Asheville, NC 28801
County: Chesterfield
Previous Orders: None
Permit/ID Number: SCR10Z4BK
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-90 (A) and Water Pollution Control Permits Regulation, S.C. Code Ann Regs. 61-9.122.41(a) and (e).

Summary: Centerfield Cooper Solar (Individual/Entity) is responsible for land-disturbing activities at the Centerfield Cooper Solar construction site (Site), located in Chesterfield County, South Carolina. On December 6, 2021, a Notice of Alleged Violation (NOAV) was issued as a result of unsatisfactory conditions observed during Department inspection of the Site. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulations as follows: discharged sediment into the environment other than in compliance with a Department issued permit, failed to comply

with all conditions of the National Pollutant Discharge Elimination System (NPDES) Permit, and failed to install and maintain all controls in accordance with the approved stormwater pollution prevention plan (SWPPP).

Action: The Individual/Entity is required to: complete permanent stabilization of the Site by August 5, 2022; submit a report signed by the Professional Engineer who prepared the SWPPP by September 5, 2022, stating that the Site is in compliance with the approved SWPPP and associated NPDES Permit; and submit an approvable and administratively complete Notice of Termination (NOT) by September 5, 2022. The Department has assessed a total civil penalty in the amount of eight thousand dollars (\$8,000.00). The Individual/Entity shall pay a civil penalty in the amount of eight thousand dollars (**\$8,000.00**) by June 5, 2022.

Update: The Individual/Entity has submitted payment of the civil penalty.

39) Order Type and Number: Consent Order 22-028-W
Order Date: May 5, 2022
Individual/Entity: **Town of Jefferson**
Facility: Town of Jefferson WWTF
Location: Off Highway 265
Jefferson, SC 29718
Mailing Address: P.O. Box 306
Jefferson, SC 29718
County: Chesterfield
Previous Orders: 20-027-W (\$1,000.00)
19-051-W (\$700.00)
Permit/ID Number: SC0024767
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d), Water Pollution Control Permits, S.C. Code Ann Regs 61-9.122.41(a) and NPDES Permit SC0024767

Summary: Town of Jefferson (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) in Chesterfield County, South Carolina. On February 17, 2022, a Notice of Alleged Violation (NOAV) was issued as a result of ammonia-nitrogen (ammonia) violations reported on discharge monitoring reports (DMRs) submitted to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulations as follows: failed to comply with the effluent limitations of its National Pollutant Discharge Elimination System (NPDES) Permit SC0024767.

Action: The Individual/Entity is required to: submit written notification of the completion date all corrective actions necessary to resolve the effluent violations by June 4, 2022; conduct a six (6) monitoring event compliance confirmation period upon completion of corrective actions; and implement engineered upgrades to the WWTF should additional violations be observed during the compliance confirmation period. The Department has assessed a total civil penalty in the amount of six thousand dollars (\$6,000.00). The Individual/Entity shall pay a civil penalty in the amount of six thousand dollars (**\$6,000.00**) by June 4, 2022.

Update: The Individual/Entity has submitted notification of the corrective action completion date and has paid the assessed civil penalty.

40) Order Type and Number: Consent Order 22-029-W
Order Date: May 11, 2022
Individual/Entity: **Edgefield County Water & Sewer Authority**
Facility: Brooks Street WWTP
Location: On Brooks Street, in Edgefield, SC
Mailing Address: P.O. Box 416
Edgefield, SC 29824
County: Edgefield
Previous Orders: None
Permit/ID Number: SC0025330
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110 (d) and Water Pollution Control Permits Regulation, S.C. Code Ann Regs. 61-9.122.41(a)

Summary: Edgefield County Water & Sewer Authority (Individual/Entity) is responsible for the proper operation and maintenance of a wastewater treatment plant (WWTP) located on Brooks Street in Edgefield County, South Carolina. On March 4, 2022, a Notice of Alleged Violation (NOAV) was issued as a result of chronic toxicity (CTOX) violations reported on discharge monitoring reports (DMRs) submitted to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulations as follows: failed to comply with effluent limitations of NPDES Permit SC0025330.

Action: The Individual/Entity is required to: submit written notification of the completion date for all corrective actions necessary to resolve the violations by June 11, 2022; conduct a six (6) monitoring event compliance confirmation period upon completion of corrective actions; and implement engineered upgrades to the WWTF should additional violations be observed during the compliance confirmation period. The Department has assessed a total civil penalty in the amount of five thousand six hundred dollars (\$5,600.00). The Individual/Entity shall pay a civil penalty in the amount of five thousand six hundred dollars (**\$5,600.00**) by June 11, 2022.

Update: The Individual/Entity has submitted notification of the corrective action completion date and has paid the assessed civil penalty.

41) Order Type and Number: Consent Order 22-030-W
Order Date: May 23, 2022
Individual/Entity: **Lowcountry Regional Water System**
Facility: Town of Yemassee WWTF
Location: East side of town at the end of Railroad Avenue
Mailing Address: P.O. Box 647
Hampton, SC 29924-3516
County: Hampton
Previous Orders: None
Permit/ID Number: SC0025950
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-110 (d); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a)

Summary: Lowcountry Regional Water System (Individual/Entity) is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Hampton County, South Carolina. On September 30, 2021, a Notice of Violation (NOV) was issued as a result of violations of the permitted discharge limits for ammonia-nitrogen (ammonia) and ultimate oxygen demand (UOD) as 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 effluent discharge limits of its National Pollutant Discharge Elimination System permit.

Action: The Individual/Entity is required to: submit a written notification of the completion date for all corrective actions necessary to resolve the violations by June 23, 2022; conduct a six (6) event compliance confirmation period upon completion of corrective actions; and implement engineered upgrades to the WWTF should additional violations be observed during the compliance confirmation period. The Department has assessed a total civil penalty in the amount of five thousand six hundred dollars (\$5,600.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand eight hundred **(\$2,800.00)** by June 23, 2022 and pay a stipulated penalty in the amount of two thousand eight hundred dollars (\$2,800.00) should any requirement of the Order not be met.

Update: None

42) <u>Order Type and Number:</u>	Consent Order 22-031-W
<u>Order Date:</u>	May 23, 2022
<u>Individual/Entity:</u>	Lakeview Steakhouse LLC
<u>Facility:</u>	Lakeview Steakhouse WWTF
<u>Location:</u>	Off Highway 14 North of Greer Greer, SC 29651
<u>Mailing Address:</u>	P.O. Box 117 Greer, SC 29652
<u>County:</u>	Greenville
<u>Previous Orders:</u>	None
<u>Permit/ID Number:</u>	SC0030465
<u>Violations Cited:</u>	Pollution Control Act, S.C. Code Ann. § 48-1-110(d), Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.21(d), and National Pollutant Discharge Elimination System (NPDES) Permit SC0030465.

Summary: Lakeview Steakhouse LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) in Greenville County, South Carolina. On January 10, 2022, a Notice of Violation (NOV) was issued for failure to reapply for permit coverage within one hundred eighty (180) days before the existing permit expires. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulations as follows: failed to submit an application for renewal of the NPDES Permit at least one hundred eighty (180) days before the existing permit expires.

Action: The Individual/Entity is required to: continue operating the WWTF in accordance with the most recent NPDES permit until a new permit becomes effective; Submit an administratively complete application for renewal of NPDES Permit SC0030465 by June 30, 2022; and by May 31, 2022 and every thirty (30) days thereafter ,

submit a summary status report on the progression of sampling, testing, and administrative processes necessary for submission of an administratively complete application for renewal of NPDES Permit SC0030465. The Department has assessed a total civil penalty in the amount of one thousand dollars (\$1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars (**\$1,000.00**) by June 22, 2022.

Update: The Individual/Entity has paid the civil penalty in full and submitted proper summary reports regarding application for permit renewal. The Individual/Entity has also submitted an administratively complete application for permit renewal.

BUREAU OF AIR QUALITY

43) Order Type and Number: Consent Order 22-009-A
Order Date: April 25, 2022
Individual/Entity: **WCC of Mayesville, LLC**
Facility: WCC of Mayesville, LLC
Location: 4845 Florence Highway
Mayesville, SC 29104
Mailing Address: P.O. Box 148
Mayesville, SC 29104
County: Sumter
Previous Orders: 17-005-A (\$7,650.00)
Permit/ID Number: 2140-0097
Violations Cited: S.C. Code Ann. Regs. 61-30, Section G(3)(b), and S.C. Code Ann. Regs 61-62.1, Section II, *Permit Requirements*

Summary: WCC of Mayesville, LLC (Individual/Entity), manufactures prefabricated wooden cabinets at its facility located Sumter County, South Carolina. On September 21, 2020, the Department conducted an inspection. The Individual/Entity violated South Carolina Air Pollution Control Regulation, as follows: failed to pay permit fees for fiscal years 2018, 2019, 2020, and 2022.

Action: The Individual/Entity is required to: henceforth pay all Air Quality permit fees and stay up to date on all fiscal year payments; and pay Fiscal Year 2018, 2019, 2020, and 2022 annual permit fees in the amount of five thousand six hundred and eighty-two dollars and forty-four cents (\$5,682.44) within one hundred and twenty (120) days of the execution date of this Order.

Update: None

44) Order Type and Number: Consent Order 22-010-A
Order Date: May 12, 2022
Individual/Entity: **BJU, Inc., d.b.a. Bob Jones University**
Facility: BJU, Inc., d/b/a Bob Jones University
Location: 1700 Wade Hampton Boulevard
Greenville, SC 29614-1000
Mailing Address: Same
County: Greenville

Previous Orders: None
Permit/ID Number: 1200-0245
Violations Cited: S.C. Code Ann. Regs. 61-62.1, Section II,
Permit Requirements

Summary: BJU, Inc., d.b.a. Bob Jones University (Individual/Entity), is a private university located in Greenville County, South Carolina. On November 17, 2021, a Department inspector conducted an inspection. The Individual/Entity has violated South Carolina Air Pollution Control Regulations, as follows: failed to record pressure drop readings for the dry filters and the dust collector on a daily basis; failed to maintain records of operation and maintenance checks performed on the dry filters and the dust collector; failed to provide fuel delivery information or fuel certification records necessary to determine facility wide NO_x emissions; and failed to perform the 2020 annual facility equipment review by the January 31st deadline.

Action: The Individual/Entity is required to: comply with all terms and conditions of State Operating Permit 1200-0245. The Department has assessed a total civil penalty in the amount of five thousand dollars (\$5,000.00). The Individual/Entity shall pay a penalty in the amount of five thousand dollars (**\$5,000.00**).

Update: The civil penalty was paid in full on May 11, 2022.

BUREAU OF ENVIRONMENTAL HEALTH SERVICES

Food Safety Enforcement

45) Order Type and Number: Administrative Order 22-14-FOOD
Order Date: May 12, 2022
Individual/Entity: **Randall Durden and Cassidy Rowe**
Facility: Double D's Dogs and Catering
Location: 625 Cottontail Trail
Myrtle Beach, SC 29588
Mailing Address: 568 George Bishop Parkway
Myrtle Beach, SC 29579
County: Horry
Previous Orders: None
Permit Number: 26-204-14293
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Double D's Dogs and Catering (Individual/Entity) is a mobile food unit located in Horry County, South Carolina. The Department conducted an investigation on February 16, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: provided food to the public without a valid permit issued 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. The Department has assessed a total civil penalty in the amount of one thousand dollars

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

Update: On June 16, 2022, the Department issued a payment demand letter for the outstanding civil penalty.

46) Order Type and Number: Consent Order 22-17-FOOD
Order Date: April 1, 2022
Individual/Entity: **Dirty Don's Oyster Bar & Grill**
Facility: Dirty Don's Oyster Bar & Grill
Location: 661 Main Street
North Myrtle Beach, SC 29582
Mailing Address: Same
County: Horry
Previous Orders: None
Permit Number: 26-206-14162
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Dirty Don's Oyster Bar & Grill (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on June 9, 2021, January 27, 2022, and February 4, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to provide individual disposable towels at each hand washing sink or group of adjacent handwashing sinks.

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

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

47) Order Type and Number: Consent Order 22-21-FOOD
Order Date: April 1, 2022
Individual/Entity: **Fatz**
Facility: Fatz
Location: 942 E. Main Street
Lexington, SC 29072
Mailing Address: 1361 West Wade Hampton Boulevard
Suite F, Box 6
Greer, SC 29650
County: Lexington
Previous Orders: 22-01-FOOD (\$800.00)
Permit Number: 32-206-06971
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Fatz (Individual/Entity) operates a restaurant located in Lexington County, South Carolina. The Department conducted inspections on November 15, 2021, December 14, 2021, December 20, 2021, February 8, 2022, February 17, 2022, March 3,

2022, and March 10, 2022. 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; failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling; failed to maintain the premises free of insects, rodents, and other pests; failed to ensure that equipment is maintained in a state of repair and condition that meets the regulation requirements; and 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. The Department has assessed a total civil penalty in the amount of two thousand seven hundred fifty dollars (\$2,750.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand seven hundred fifty dollars (**\$2,750.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

48) <u>Order Type and Number:</u>	Consent Order 22-26-FOOD
<u>Order Date:</u>	April 5, 2022
<u>Individual/Entity:</u>	Domino's #5608
<u>Facility:</u>	Domino's #5608
<u>Location:</u>	7400 Garners Ferry Road Columbia, SC 29209
<u>Mailing Address:</u>	4034 Enterprise Way, Suite 180 Flowery Branch, GA 30542
<u>County:</u>	Richland
<u>Previous Orders:</u>	None
<u>Permit Number:</u>	40-206-06086
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-25

Summary: Domino's #5608 (Individual/Entity) operates a restaurant located in Richland County, South Carolina. The Department conducted inspections on February 18, 2022, February 28, 2022, and March 10, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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. The Department has assessed a total civil penalty in the amount of eight hundred dollars (\$800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars (**\$800.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

49) <u>Order Type and Number:</u>	Consent Order 22-07-FOOD
<u>Order Date:</u>	April 6, 2022
<u>Individual/Entity:</u>	Persis Biryani Grill
<u>Facility:</u>	Persis Biryani Grill

Location: 1728 Bush River Road
Columbia, SC 29210
Mailing Address: Same
County: Lexington
Previous Orders: None
Permit Number: 32-206-06984
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Persis Biryani Grill (Individual/Entity) operates a restaurant located in Lexington County, South Carolina. The Department conducted inspections on February 10, 2022, February 11, 2022, and February 18, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that the handwashing sinks were accessible at all times; 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. The Department has assessed a total civil penalty in the amount of four hundred dollars (\$400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars **(\$400.00)**.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

50) Order Type and Number: Consent Order 22-12-FOOD
Order Date: April 6, 2022
Individual/Entity: **Riveras Panaderia**
Facility: Riveras Panaderia
Location: 1126 Mack Street
Gaston, SC 29053
Mailing Address: 1807 Decker Boulevard
Columbia, SC 29206
County: Lexington
Previous Orders: None
Permit Number: 32-206-07099
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Riveras Panaderia (Individual/Entity) operates a restaurant located in Lexington County, South Carolina. The Department conducted inspections on January 6, 2022, January 11, 2022, January 12, 2022, and January 14, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: 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. The Department has assessed a total civil penalty in the amount of eight hundred dollars (\$800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars **(\$800.00)**.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

51) Order Type and Number: Consent Order 22-18-FOOD
Order Date: April 7, 2022
Individual/Entity: **Sunday Best Jamaican Cuisine**
Facility: Sunday Best Jamaican Cuisine
Location: 127 Highway 17 North
North Myrtle Beach, SC 29588
Mailing Address: Same
County: Horry
Previous Orders: None
Permit Number: 26-206-14101
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Sunday Best Jamaican Cuisine (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on July 13, 2021, July 23, 2021, February 9, 2022, and February 18, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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. The Department has assessed a total civil penalty in the amount of one thousand, six hundred dollars (\$1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, six hundred dollars (**\$1,600.00**).

Update: The facility is current on their payment plan.

52) Order Type and Number: Consent Order 22-20-FOOD
Order Date: April 7, 2022
Individual/Entity: **Red Rooster Sports Bar**
Facility: Red Rooster Sports Bar
Location: 7500 Wilson Boulevard
Columbia, SC 29203
Mailing Address: Same
County: Richland
Previous Orders: None
Permit Number: 40-206-08642
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Red Rooster Sports Bar (Individual/Entity) operates a restaurant located in Richland County, South Carolina. The Department conducted inspections on January 28, 2022, February 3, 2022, February 11, 2022, and February 18, 2022. 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; 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. The Department has assessed a total civil penalty in the amount of eight hundred dollars (\$800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars (**\$800.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

53) Order Type and Number: Consent Order 22-10-FOOD
Order Date: April 13, 2022
Individual/Entity: **Anderson Wings, LLC**
Facility: Anderson Wings, LLC
Location: 119 Interstate Boulevard
Anderson, SC 29621
Mailing Address: 205 Regency Executive Park Drive
Suite 204
Charlotte, NC 28217
County: Anderson
Previous Orders: 2018-206-01-005 (\$1,000.00);
2019-206-01-012 (\$1,750.00);
2019-206-01-052 (\$500.00)
Permit Number: 04-206-04218
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Anderson Wings, LLC (Individual/Entity) operates a restaurant located in Anderson County, South Carolina. The Department conducted inspections on September 30, 2021, January 6, 2022, and January 14, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that each handwashing sink or group of two (2) adjacent handwashing sinks was provided with a supply of hand cleaning, liquid, powder or bar soap; and failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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. The Department has assessed a total civil penalty in the amount of one thousand, two hundred fifty dollars (\$1,250.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, two hundred fifty dollars (**\$1,250.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

54) Order Type and Number: Consent Order 22-23-FOOD
Order Date: April 13, 2022
Individual/Entity: **Water's Edge Restaurant**
Facility: Water's Edge Restaurant
Location: 1407 Shrimp Boat Lane
Mount Pleasant, SC 29464
Mailing Address: 56 Wentworth Street, Suite 200
Charleston, SC 29401
County: Charleston
Previous Orders: None

Permit Number: 10-206-11731
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Water's Edge Restaurant (Individual/Entity) operates a restaurant located in Charleston County, South Carolina. The Department conducted inspections on November 16, 2021, November 23, 2021, January 26, 2022, February 4, 2022, and February 14, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling; 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. The Department has assessed a total civil penalty in the amount of one thousand, two hundred dollars (\$1,200.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, two hundred dollars (**\$1,200.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

55) Order Type and Number: Consent Order 22-27-FOOD
Order Date: April 19, 2022
Individual/Entity: **Kings Sushi II**
Facility: Kings Sushi II
Location: 801 Highway 17 North
North Myrtle Beach, SC 29582
Mailing Address: 224 Haley Lane
Conway, SC 29527
County: Horry
Previous Orders: 2018-206-06-014 (\$800.00)
Permit Number: 26-206-13150
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Kings Sushi II (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on January 7, 2022, January 14, 2022, and March 7, 2022. 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. The Department has assessed a total civil penalty in the amount of one thousand dollars (\$1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars (**\$1,000.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

56) Order Type and Number: Consent Order 22-30-FOOD

<u>Order Date:</u>	April 19, 2022
<u>Individual/Entity:</u>	Scott's BBQ
<u>Facility:</u>	Scott's BBQ
<u>Location:</u>	2734 Hemingway Highway Hemingway, SC 29554
<u>Mailing Address:</u>	Same
<u>County:</u>	Williamsburg
<u>Previous Orders:</u>	2017-206-06-139 (\$1,250.00); 2019-206-06-107 (\$250.00); 2019-206-06-166 (\$1,000.00)
<u>Permit Number:</u>	45-206-00442
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-25

Summary: Scott's BBQ (Individual/Entity) operates a restaurant located in Williamsburg County, South Carolina. The Department conducted inspections on October 8, 2021, October 15, 2021, February 16, 2022, February 24, 2022, and March 4, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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. The Department has assessed a total civil penalty in the amount of three thousand dollars (\$3,000.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand dollars (**\$3,000.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

57) <u>Order Type and Number:</u>	Consent Order 22-29-FOOD
<u>Order Date:</u>	April 21, 2022
<u>Individual/Entity:</u>	La Vinotinto Restaurant
<u>Facility:</u>	La Vinotinto Restaurant
<u>Location:</u>	1311 North Kings Highway Myrtle Beach, SC 29577
<u>Mailing Address:</u>	Same
<u>County:</u>	Horry
<u>Previous Orders:</u>	None
<u>Permit Number:</u>	26-206-14326
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-25

Summary: La Vinotinto Restaurant (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on June 23, 2021, July 1, 2021, and March 2, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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. The Department has assessed a total civil penalty in the amount of eight hundred dollars

(\$800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars (**\$800.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

58) Order Type and Number: Consent Order 22-28-FOOD
Order Date: April 26, 2022
Individual/Entity: **Ashe Street Convenience**
Facility: Ashe Street Convenience
Location: 63 Ashe Street
Charleston, SC 29403
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit Number: 10-206-08579
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Ashe Street Convenience (Individual/Entity) operates a restaurant located in Charleston County, South Carolina. The Department conducted inspections on February 16, 2022, February 25, 2022, and March 7, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to provide a written plan for the restriction, exclusion, and re-instatement of food employees when they have symptoms and/or diseases that are transmissible through food; failed to provide a test kit or other device that accurately measures the concentration of MG/L of sanitizing solutions; and failed to ensure that the retail food establishment had written procedures for employees to follow when responding to vomiting or diarrheal events, that involve the discharge of vomitus or fecal matter onto surfaces in the retail food establishment.

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. The Department has assessed a total civil penalty in the amount of eight hundred dollars (\$800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars (**\$800.00**).

Update: On June 16, 2022, the Department issued a payment demand letter for the outstanding civil penalty.

59) Order Type and Number: Consent Order 22-33-FOOD
Order Date: April 26, 2022
Individual/Entity: **Blue Tolok Grill & Bar, LLC**
Facility: Blue Tolok Grill & Bar, LLC
Location: 304 Highway 28 Bypass
Anderson, SC 29624
Mailing Address: Same
County: Anderson
Previous Orders: None
Permit Number: 04-206-04217
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Blue Tolok Grill & Bar, LLC (Individual/Entity) operates a restaurant located in Anderson County, South Carolina. The Department conducted inspections on March 9, 2022, March 15, 2022, and March 22, 2022. 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. The Department has assessed a total civil penalty in the amount of eight hundred dollars (\$800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars (**\$800.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

60)	<u>Order Type and Number:</u>	Consent Order 22-34-FOOD
	<u>Order Date:</u>	April 28, 2022
	<u>Individual/Entity:</u>	Circle K #775
	<u>Facility:</u>	Circle K #775
	<u>Location:</u>	105 Main Road Charleston, SC 29445
	<u>Mailing Address:</u>	1100 Situs Court, Suite 100 Raleigh, NC 27606
	<u>County:</u>	Charleston
	<u>Previous Orders:</u>	None
	<u>Permit Number:</u>	10-206-09835
	<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-25

Summary: Circle K #775 (Individual/Entity) operates a restaurant located in Charleston County, South Carolina. The Department conducted inspections on March 8, 2022, March 18, 2022, March 25, 2022, and April 1, 2022. 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. The Department has assessed a total civil penalty in the amount of eight hundred dollars (\$800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars (**\$800.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

61)	<u>Order Type and Number:</u>	Consent Order 22-42-FOOD
	<u>Order Date:</u>	April 28, 2022
	<u>Individual/Entity:</u>	Black Magic Café
	<u>Facility:</u>	Black Magic Café
	<u>Location:</u>	1130 Folly Road Charleston, SC 29412
	<u>Mailing Address:</u>	2245 Portside Way

Charleston, SC 29407
County: Charleston
Previous Orders: None
Permit Number: 10-206-10219
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Black Magic Café (Individual/Entity) operates a restaurant located in Charleston County, South Carolina. The Department conducted inspections on March 22, 2022, March 24, 2022, and March 28, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods were maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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. The Department has assessed a total civil penalty in the amount of eight hundred dollars (\$800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars (**\$800.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

62) Order Type and Number: Consent Order 22-35-FOOD
Order Date: May 5, 2022
Individual/Entity: **Domino's**
Facility: Domino's
Location: 621 St. Andrews Road
Columbia, SC 29210
Mailing Address: 4034 Enterprise Way, Suite 180
Flowery Branch, GA 30542
County: Lexington
Previous Orders: None
Permit Number: 32-206-06453
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Domino's (Individual/Entity) operates a restaurant located in Lexington County, South Carolina. The Department conducted inspections on March 16, 2022, March 24, 2022, and April 1, 2022. 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. The Department has assessed a total civil penalty in the amount of four hundred dollars (\$400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars (**\$400.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

63) Order Type and Number: Consent Order 22-41-FOOD

Order Date: May 11, 2022
Individual/Entity: **McDonald's #18049**
Facility: McDonald's #18049
Location: 428 South Main Street
Belton, SC 29627
Mailing Address: 3414 Common Street
Lake Charles, LA 70607
County: Anderson
Previous Orders: None
Permit Number: 04-206-04667
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: McDonald's #18049 (Individual/Entity) operates a restaurant located in Lexington County, South Carolina. The Department conducted inspections on October 9, 2021, October 27, 2021, March 2, 2022, March 9, 2022, and March 17, 2022. 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. The Department has assessed a total civil penalty in the amount of one thousand, two hundred dollars (\$1,200.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, two hundred dollars (**\$1,200.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

64) Order Type and Number: Consent Order 22-31-FOOD
Order Date: May 13, 2022
Individual/Entity: **La Estrella**
Facility: La Estrella
Location: 1921 Airport Boulevard
West Columbia, SC 29169
Mailing Address: Same
County: Lexington
Previous Orders: None
Permit Number: 32-206-05018
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: La Estrella (Individual/Entity) operates a restaurant located in Lexington County, South Carolina. The Department conducted inspections on January 11, 2022, January 24, 2022, March 7, 2022, and March 17, 2022. 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; 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 time/temperature control for safety foods were maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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. The Department has assessed a total civil penalty in the amount of one thousand, eight

hundred dollars (\$1,800.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, eight hundred dollars (**\$1,800.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

65) Order Type and Number: Consent Order 22-36-FOOD
Order Date: May 13, 2022
Individual/Entity: **Riveras Supermercado**
Facility: Riveras Supermercado
Location: 1618 Airport Boulevard
West Columbia, SC 29169
Mailing Address: 1807 Decker Boulevard
Columbia, SC 29206
County: Lexington
Previous Orders: None
Permit Number: 32-211-07191
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Riveras Supermercado (Individual/Entity) operates a restaurant located in Lexington County, South Carolina. The Department conducted inspections on February 22, 2022, March 4, 2022, and March 9, 2022. 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; 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. The Department has assessed a total civil penalty in the amount of eight hundred dollars (\$800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars (**\$800.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

66) Order Type and Number: Consent Order 22-62-FOOD
Order Date: May 13, 2022
Individual/Entity: **Riveras Supermercado**
Facility: Riveras Supermercado
Location: 1618 Airport Boulevard
West Columbia, SC 29169
Mailing Address: 1807 Decker Boulevard
Columbia, SC 29206
County: Lexington
Previous Orders: 22-36-FOOD (\$800.00)
Permit Number: 32-211-07191
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Riveras Supermercado (Individual/Entity) operates a restaurant located in Lexington County, South Carolina. The Department conducted inspections on February 22, 2022, April 18, 2022, April 19, 2022, April 27, 2022, and May 5, 2022. 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; failed to ensure that a person in charge is certified by a food handler certification program that is recognized by the Conference for Food Protection; 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. The Department has assessed a total civil penalty in the amount of three thousand, two hundred fifty dollars (\$3,250.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand, two hundred fifty dollars (**\$3,250.00**).

Update: On June 16, 2022, the Department issued a payment demand letter for the outstanding civil penalty.

67)	<u>Order Type and Number:</u>	Consent Order 22-40-FOOD
	<u>Order Date:</u>	May 19, 2022
	<u>Individual/Entity:</u>	Persis Biryani Grill
	<u>Facility:</u>	Persis Biryani Grill
	<u>Location:</u>	1728 Bush River Road Columbia, SC 29210
	<u>Mailing Address:</u>	Same
	<u>County:</u>	Lexington
	<u>Previous Orders:</u>	22-07-FOOD (\$400.00)
	<u>Permit Number:</u>	32-206-06984
	<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-25

Summary: Persis Biryani Grill (Individual/Entity) operates a restaurant located in Lexington County, South Carolina. The Department conducted an inspection on April 5, 2022. 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. The Department has assessed a total civil penalty in the amount of five hundred dollars (\$500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars (**\$500.00**) by June 22, 2022.

Update: If payment is not received by June 22, 2022, the Department will issue a payment demand letter for the outstanding civil penalty.

68)	<u>Order Type and Number:</u>	Consent Order 22-39-FOOD
	<u>Order Date:</u>	May 20, 2022
	<u>Individual/Entity:</u>	Irene's of Newberry
	<u>Facility:</u>	Irene's of Newberry
	<u>Location:</u>	2895 Main Street

	Newberry, SC 29108
<u>Mailing Address:</u>	Same
<u>County:</u>	Newberry
<u>Previous Orders:</u>	None
<u>Permit Number:</u>	36-206-01400
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-25

Summary: Irene's of Newberry (Individual/Entity) operates a restaurant located in Newberry County, South Carolina. The Department conducted a site visit on April 5, 2022. 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. The Department has assessed a total civil penalty in the amount of five hundred dollars (\$500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars (**\$500.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

69) <u>Order Type and Number:</u>	Consent Order 22-32-FOOD
<u>Order Date:</u>	May 23, 2022
<u>Individual/Entity:</u>	El Titanic American & Mexican
<u>Facility:</u>	El Titanic American & Mexican
<u>Location:</u>	605 South Main Street Belton, SC 29627
<u>Mailing Address:</u>	Same
<u>County:</u>	Anderson
<u>Previous Orders:</u>	2017-206-01-003 (\$800.00); 2018-206-01-001 (\$2,000.00); 2018-206-01-056 (\$1,000.00); 2019-206-01-067 (\$2,750.00)
<u>Permit Number:</u>	04-206-02961
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-25

Summary: El Titanic American & Mexican (Individual/Entity) operates a restaurant located in Anderson County, South Carolina. The Department conducted inspections on December 9, 2021, December 15, 2021, February 17, 2022, and March 2, 2022. 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 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. The Department has assessed a total civil penalty in the amount of two thousand dollars (\$2,000.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand dollars (**\$2,000.00**).

Update: The Individual/Entity is current on their payment plan.

70) Order Type and Number: Consent Order 22-47-FOOD
Order Date: May 23, 2022
Individual/Entity: **Fatz**
Facility: Fatz
Location: 1615 Sandifer Boulevard
Seneca, SC 29678
Mailing Address: 1361 W. Wade Hampton Blvd., Suite F #6
Greer, SC 29650
County: Oconee
Previous Orders: None
Permit Number: 37-206-01321
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Fatz (Individual/Entity) operates a restaurant located in Oconee County, South Carolina. The Department conducted inspections on March 22, 2022, April 1, 2022, and April 8, 2022. 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. The Department has assessed a total civil penalty in the amount of four hundred dollars (\$400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars (**\$400.00**) by June 28, 2022.

Update: If payment is not received by June 28, 2022, the Department will issue a payment demand letter for the outstanding civil penalty.

71) Order Type and Number: Consent Order 22-57-FOOD
Order Date: May 24, 2022
Individual/Entity: **Bangkok House**
Facility: Bangkok House
Location: 318 North Kings Highway
Myrtle Beach, SC 29577
Mailing Address: Same
County: Horry
Previous Orders: 2017-206-06-034 (\$800.00)
Permit Number: 26-206-08947
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Bangkok House (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on March 24, 2022, April 1, 2022, and April 8, 2022. 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. The Department has assessed a total civil penalty in the amount of five hundred dollars

(\$500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars (**\$500.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

72) Order Type and Number: Consent Order 22-45-FOOD
Order Date: May 26, 2022
Individual/Entity: **Bojangles #912**
Facility: Bojangles #912
Location: 4131 Clemson Boulevard
Anderson, SC 29621
Mailing Address: 7750 North MacArthur Boulevard, Suite
120-223
Irving, TX 75063
County: Anderson
Previous Orders: 22-04-FOOD (\$1,000.00)
Permit Number: 04-206-04727
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Bojangles #912 (Individual/Entity) operates a restaurant located in Anderson County, South Carolina. The Department conducted inspections on March 23, 2022, March 29, 2022, and April 7, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to convey sewage to the point of disposal through an approved sanitary sewage system or other system, including use of sewage transport vehicles, waste retention tanks, pumps, pipes, hoses, and connections that are constructed, maintained, and operated according to law.

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. The Department has assessed a total civil penalty in the amount of one thousand dollars (\$1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars (**\$1,000.00**) by June 28, 2022.

Update: If payment is not received by June 28, 2022, the Department will issue a payment demand letter for the outstanding civil penalty.

73) Order Type and Number: Consent Order 22-56-FOOD
Order Date: May 26, 2022
Individual/Entity: **Fujisan Sushi**
Facility: Fujisan Sushi
Location: 3501 Belle Terre Boulevard
Myrtle Beach, SC 29579
Mailing Address: 1422 Bloomfield Avenue
Sante Fe Springs, CA 90670
County: Horry
Previous Orders: None
Permit Number: 26-206-14380
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Fujisan Sushi (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on March 28, 2022, April 7, 2022, and April 15, 2022. 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; and failed to comply with the Hazard Analysis and Critical Control Point (HACCP) plan and procedures that are submitted and approved as a basis for the modification or waiver; and maintain and provide to the Department, upon request, records that demonstrate the HACCP plan is being employed.

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. The Department has assessed a total civil penalty in the amount of eight hundred dollars (\$800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars **(\$800.00)**.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

74) <u>Order Type and Number:</u>	Consent Order 22-60-FOOD
<u>Order Date:</u>	May 26, 2022
<u>Individual/Entity:</u>	Coastal Crust
<u>Facility:</u>	Coastal Crust
<u>Location:</u>	218 Scott Street Mount Pleasant, SC 29464
<u>Mailing Address:</u>	219 Simmons Street Mount Pleasant, SC 29464
<u>County:</u>	Charleston
<u>Previous Orders:</u>	None
<u>Permit Number:</u>	10-206-09744
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-25

Summary: Coastal Crust (Individual/Entity) operates a restaurant located in Charleston County, South Carolina. The Department conducted inspections on April 4, 2022, April 14, 2022, and April 21, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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. The Department has assessed a total civil penalty in the amount of eight hundred dollars (\$800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars **(\$800.00)**.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

75) <u>Order Type and Number:</u>	Consent Order 22-38-FOOD
<u>Order Date:</u>	May 31, 2022
<u>Individual/Entity:</u>	Holiday Inn Express & Suites
<u>Facility:</u>	Holiday Inn Express & Suites

Location: 300 North Creek Boulevard
Greenwood, SC 29649
Mailing Address: 109 Destination Boulevard
Anderson, SC 29621
County: Greenwood
Previous Orders: None
Permit Number: 24-206-03103
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Holiday Inn Express & Suites (Individual/Entity) operates a restaurant located in Greenwood County, South Carolina. The Department conducted inspections on March 16, 2022, March 24, 2022, and April 1, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety foods were maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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. The Department has assessed a total civil penalty in the amount of eight hundred dollars (\$800.00). The Individual/Entity shall pay a civil penalty in the amount of eight hundred dollars (**\$800.00**) by July 5, 2022.

Update: If payment is not received by July 5, 2022, the Department will issue a payment demand letter for the outstanding civil penalty.

76) Order Type and Number: Consent Order 22-54-FOOD
Order Date: May 31, 2022
Individual/Entity: **San Jose**
Facility: San Jose
Location: 1937 Augusta Highway
Lexington, SC 29072
Mailing Address: 107 Maple Road
Lexington, SC 29073
County: Lexington
Previous Orders: None
Permit Number: 32-206-07325
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: San Jose (Individual/Entity) operates a restaurant located in Lexington County, South Carolina. The Department conducted inspections on November 9, 2021, March 22, 2022, April 1, 2022, April 8, 2022, and April 29, 2022. 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; and failed to ensure that the floor and wall junction was coved and closed to no larger than one (1) thirty-second inch (1 mm).

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. The Department has assessed a total civil penalty in the amount of four hundred dollars (\$400.00). The Individual/Entity shall pay a civil penalty in the amount of four hundred dollars (**\$400.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

77) Order Type and Number: Consent Order 22-61-FOOD
Order Date: May 31, 2022
Individual/Entity: **La Bendicion**
Facility: La Bendicion
Location: 1251 Boston Avenue
West Columbia, SC 29170
Mailing Address: Same
County: Lexington
Previous Orders: None
Permit Number: 32-206-07278
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: La Bendicion (Individual/Entity) operates a restaurant located in Lexington County, South Carolina. The Department conducted inspections on February 15, 2022, February 24, 2022, April 14, 2022, and April 22, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that time/temperature control for safety food was maintained at a temperature of 41 degrees F and below or 135 degrees F and above, except during preparation, cooking, or cooling.

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. The Department has assessed a total civil penalty in the amount of one thousand, six hundred dollars (\$1,600.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, six hundred dollars (**\$1,600.00**).

Update: The Individual/Entity is current on their payment plan.

On-Site Wastewater Enforcement

78) Order Type and Number: Administrative Order 22-009-OSWW
Order Date: March 15, 2022
Individual/Entity: **Tabitha Stancil**
Facility: Tabitha Stancil
Location: Eleven Oaks Drive
Westminster, SC 29693
Mailing Address: Multiple
County: Oconee
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Tabitha Stancil (Individual/Entity) owns property located in Oconee County, South Carolina. The Department conducted an investigation on December 12, 2021, and observed a camper occupied for more than two hours per day without an approved means of domestic wastewater treatment and disposal. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows:

failed to ensure that any building, dwelling, or other structure occupied for more than two hours per day was connected to an approved method of domestic wastewater treatment and disposal.

Action: The Individual/Entity is required to apply for a Permit to construct an OSWW system within five (5) days; or immediately vacate the camper to eliminate the flow of domestic wastewater. The Department has assessed a total civil penalty in the amount of five thousand dollars (\$5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars (**\$5,000.00**) should any requirement of the Order not be met.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

79) <u>Order Type and Number:</u>	Administrative Order 22-010-OSWW
<u>Order Date:</u>	March 15, 2022
<u>Individual/Entity:</u>	Teresa Page
<u>Facility:</u>	Teresa Page
<u>Location:</u>	Tory Hill Road Loris, SC 29569
<u>Mailing Address:</u>	11601 Cowpoke Circle Lusby, MD 29657
<u>County:</u>	Horry
<u>Previous Orders:</u>	None
<u>Permit Number:</u>	None
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-56

Summary: Teresa Page (Individual/Entity) owns property located in Horry County, South Carolina. The Department conducted an investigation on February 1, 2022, and observed a camper being occupied for more than two hours per day without being connected to an approved method of domestic wastewater treatment and disposal. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that a unit, dwelling, or other structure is occupied for more than two hours per day without being connected to an approved method of domestic wastewater treatment and disposal.

Action: The Individual/Entity is required to apply for a Permit to construct an OSWW system within five (5) days; or immediately vacate the camper to eliminate the flow of domestic wastewater. The Department has assessed a total civil penalty in the amount of five thousand dollars (\$5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars (**\$5,000.00**) should any requirement of the Order not be met.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

80) <u>Order Type and Number:</u>	Administrative Order 22-012-OSWW
<u>Order Date:</u>	March 15, 2022
<u>Individual/Entity:</u>	Harold Gault
<u>Facility:</u>	Harold Gault
<u>Location:</u>	23 Pecan Street

Mailing Address: Pacolet, SC 29372
P.O. Box 244
Pacolet Mills, SC 29373
County: Spartanburg
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Harold Gault (Individual/Entity) owns property located in Spartanburg County, South Carolina. The Department conducted an investigation on February 23, 2022, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars (\$5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars (**\$5,000.00**) should any requirement of the Order not be met.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

81) Order Type and Number: Administrative Order 22-013-OSWW
Order Date: March 21, 2022
Individual/Entity: **John W. Mize**
Facility: John W. Mize
Location: 120 and 121 Dwaine Road
Belton, SC 29627
Mailing Address: 110 Lockaby Drive
Pelzer, SC 29669
County: Anderson
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: John W. Mize (Individual/Entity) owns property located in Anderson County, South Carolina. The Department conducted an investigation on November 2, 2021 and observed domestic wastewater discharging onto the surface of the ground from a residence and a camper that was being occupied for more than two hours per day without being connected to an approved method of domestic wastewater treatment and disposal. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department; and failed to ensure that any building, dwelling, unit, or other structure occupied for more than two hours per day was connected to an approved method of domestic wastewater treatment and disposal.

Action: The Individual/Entity is required to repair the OSWW system and plumbing within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; and apply for a Permit to Construct an OSWW system for the camper within five (5) days of execution of the order; or immediately vacate the residence and camper to eliminate the flow of domestic wastewater to the surface of the ground. The Department has assessed a total civil penalty in the amount of five thousand dollars (\$5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars (**\$5,000.00**) should any requirement of the Order not be met.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

82) Order Type and Number: Administrative Order 22-014-OSWW
Order Date: March 23, 2022
Individual/Entity: **Boscaglia Properties, LLC**
Facility: Boscaglia Properties, LLC
Location: 22 Country Meadow Lane
Lexington, SC 29073
Mailing Address: 900 Bonhomme Richard Road
Lexington, SC 29072
County: Lexington
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Boscaglia Properties, LLC (Individual/Entity) owns property located in Lexington County, South Carolina. The Department conducted an investigation on February 2, 2022 and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars (\$5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars (**\$5,000.00**) should any requirement of the Order not be met.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

83) Order Type and Number: Administrative Order 22-017-OSWW
Order Date: April 19, 2022
Individual/Entity: **Cynthia York**
Facility: Cynthia York
Location: 66 Executive Drive
Greeleyville, SC 29056

Mailing Address: Same
County: Williamsburg
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Cynthia York (Individual/Entity) owns property located in Williamsburg County, South Carolina. The Department conducted an investigation on February 8, 2022 and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars (\$5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars (**\$5,000.00**) should any requirement of the Order not be met.

Update: A demand letter sent to the Individual/Entity on June 16, 2022.

84) Order Type and Number: Administrative Order 22-018-OSWW
Order Date: April 19, 2022
Individual/Entity: **Rickey Steen and Tina Steen**
Facility: Rickey Steen and Tina Steen
Location: 99 Cooper Road
Whitmire, SC 29178
Mailing Address: 48 Cooper Road
Whitmire, SC 29178
County: Newberry
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Rickey Steen and Tina Steen (Individual/Entity) owns property located in Newberry County, South Carolina. The Department conducted an investigation on March 8, 2022 and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars (\$5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars (**\$5,000.00**) should any requirement of the Order not be met.

Update: Department staff spoke with the licensed OSWW contractor who stated he has scheduled the repairs to the OSWW system for the week of June 20th, 2022.

85) Order Type and Number: Administrative Order 22-021-OSWW
Order Date: April 19, 2022
Individual/Entity: **Christopher Lipscomb and Mary Lipscomb**
Facility: Christopher Lipscomb and Mary Lipscomb
Location: 601 Sharpe Road
Columbia, SC 29203
Mailing Address: Same
County: Richland
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Christopher Lipscomb and Mary Lipscomb (Individual/Entity) own property located in Richland County, South Carolina. The Department conducted an investigation on February 2, 2022 and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars (\$5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars (**\$5,000.00**) should any requirement of the Order not be met.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

86) Order Type and Number: Administrative Order 22-023-OSWW
Order Date: April 19, 2022
Individual/Entity: **Paula Wise, Personal Representative for the Estate of Anna Wise**
Facility: Paula Wise, Personal Representative for the Estate of Anna Wise
Location: 118 Glasgow Drive
Prosperity, SC 29127
Mailing Address: 1230 Pebblebrook Drive
Newberry, SC 29108
County: Newberry
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Paula Wise, Personal Representative for the Estate of Anna Wise Individual/Entity); owns property located in Newberry County, South Carolina. The Department conducted an investigation on February 22, 2022 and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars (\$5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars (**\$5,000.00**) should any requirement of the Order not be met.

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

87)	<u>Order Type and Number:</u>	Administrative Order 22-029-OSWW
	<u>Order Date:</u>	May 12, 2022
	<u>Individual/Entity:</u>	Tita Investments
	<u>Facility:</u>	Tita Investments
	<u>Location:</u>	316 Starling Drive, Mobile Home #2 Hopkins, SC 29061
	<u>Mailing Address:</u>	P.O. Box 9286 Columbia, SC 29290
	<u>County:</u>	Richland
	<u>Previous Orders:</u>	None
	<u>Permit Number:</u>	None
	<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-56

Summary: Tita Investments (Individual/Entity) owns property located in Richland County, South Carolina. The Department conducted an investigation on April 4, 2022 and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent, domestic wastewater, or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system. The Department has assessed a total civil penalty in the amount of five thousand dollars (\$5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars (**\$5,000.00**) should any requirement of the Order not be met.

Update: A licensed contractor is scheduled to repair the week of June 20, 2022.

88)	<u>Order Type and Number:</u>	Consent Order 22-016-OSWW
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<u>Order Date:</u>	April 1, 2022
<u>Individual/Entity:</u>	Complete Well Drilling and Septic Tank/Kellie Sharpe
<u>Facility:</u>	Complete Well Drilling and Septic Tank/Kellie Sharpe
<u>Location:</u>	Saluda Shores Circle, Lot 40 Leesville, SC 29070
<u>Mailing Address:</u>	1543 Swansea Road Pelion, SC 29123
<u>County:</u>	Saluda
<u>Previous Orders:</u>	None
<u>Permit Number:</u>	None
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-56

Summary: Complete Well Drilling and Septic Tank/Kellie Sharpe (Individual/Entity) Home Comfort Systems, LLC (Individual/Entity) installed an OSWW system at property located in Saluda County, South Carolina. The Department conducted an inspection on February 24, 2022 and determined that the OSWW system was installed inconsistent with the permit and S.C. Reg 61-56. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: installed an OSWW system outside the requirements of the permit, with the vertical separation between the deepest point of effluent and the zone of saturation being less than six inches, with less than seven feet of undisturbed dirt between the wastewater infiltration trenches, and with less than two feet of earthen buffer between the septic tank and all portions of the adjacent wastewater infiltration trenches.

Action: The Individual/Entity is required to cease and desist installing OSWW systems inconsistent with the requirements of the Department issued Permit to Construct and S.C. Reg 61-56. The Department has assessed a total civil penalty in the amount of two thousand dollars (\$2,000.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand dollars (**\$2,000.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

89) <u>Order Type and Number:</u>	Consent Order 22-019-OSWW
<u>Order Date:</u>	May 5, 2022
<u>Individual/Entity:</u>	Michelle Wilson, d.b.a. Wilson's Septic Tanks Service
<u>Facility:</u>	Michelle Wilson, d.b.a. Wilson's Septic Tanks Service
<u>Location:</u>	P.O. Box 1506 Hartsville, SC 29551
<u>Mailing Address:</u>	Same
<u>County:</u>	Darlington
<u>Previous Orders:</u>	None
<u>Permit Number:</u>	None
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-56

Summary: Michelle Wilson, d.b.a. Wilson's Septic Tanks Service (Individual/Entity) installed three OSWW systems in Darlington County, South Carolina. The Department conducted a review of documents during January 2022 and determined

that not enough aggregate was installed at all three sites. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that all systems for which the licensee is responsible are constructed, repaired, and cleaned in accordance with S.C. Regulation 61-56 and Permits issued by the Department.

Action: The Individual/Entity is required to cease and desist constructing OSWW systems not in accordance with S.C. Regulation 61-56 and Permits issued by the Department. The Department has assessed a total civil penalty in the amount of one thousand, five hundred dollars (\$1,500.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, five hundred dollars (**\$1,500.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

90) <u>Order Type and Number:</u>	Consent Order 22-030-OSWW
<u>Order Date:</u>	May 5, 2022
<u>Individual/Entity:</u>	Calvin Randolph
<u>Facility:</u>	Calvin Randolph
<u>Location:</u>	1861 Old Collins Creek Road McClellanville, SC 29458
<u>Mailing Address:</u>	Same
<u>County:</u>	Charleston
<u>Previous Orders:</u>	None
<u>Permit Number:</u>	None
<u>Violations Cited:</u>	S.C. Code Ann. Regs. 61-56

Summary: Calvin Randolph (Individual/Entity) installed an OSWW system in Charleston County, South Carolina. The Department conducted an investigation on February 9, 2022 and determined that the Individual/Entity does not hold a Department issued license to construct OSWW systems and that the Department was not contacted to inspect the installation. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: engaged in the business of constructing and repairing onsite sewage treatment systems without first applying for, receiving, and subsequently maintaining a valid license to conduct such activities, as required by the Department.

Action: The Individual/Entity is required to cease and desist engaging in the business of constructing and repairing onsite sewage treatment systems without first applying for, receiving, and subsequently maintaining a valid license to conduct such activities, as required by the Department. The Department has assessed a total civil penalty in the amount of five hundred dollars (\$500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars (**\$500.00**).

Update: On June 15, 2022, Department staff issued a payment demand letter for the outstanding civil penalty.

91) <u>Order Type and Number:</u>	Consent Order 22-033-OSWW
<u>Order Date:</u>	May 24, 2022
<u>Individual/Entity:</u>	Ivan Rusev, d.b.a. Rock Solid Excavation Services, LLC

Facility: Ivan Rusev, d.b.a. Rock Solid Excavation Services, LLC
Location: 140 Wilkins Road
Campobello, SC 29322
Mailing Address: Same
County: Cherokee
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Ivan Rusev, d.b.a. Rock Solid Excavation Services, LLC (Individual/Entity) installed an OSWW system in Cherokee County, South Carolina. The Department conducted an investigation on February 10, 2022 and determined that the Individual/Entity installed portions of the OSWW system deeper than allowed on the permit. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that all systems for which the licensee is responsible are constructed in accordance with S.C. Regulation 61-56 and permits issued by the Department.

Action: The Individual/Entity is required to cease and desist allowing systems for which the licensee is responsible to be constructed in a manner not in accordance with S.C. Regulation 61-56 and Permits issued by the Department. The Department has assessed a total civil penalty in the amount of five hundred dollars (\$500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars (**\$500.00**).

Update: The Individual/Entity has met all requirements of the Order. This Order has been closed.

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

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

June 29, 2022

(X) ACTION/DECISION
() INFORMATION

I. TITLE: Request for Placement of Ganaxolone in Schedule V for Controlled Substances in South Carolina

II. SUBJECT: Placement of Ganaxolone in Schedule V for Controlled Substances

III. FACTS:

Controlled substances are governed by the South Carolina Controlled Substances Act, Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule V substances are listed in Section 44-53-270 of the South Carolina Code of Laws. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances shall be made," controlled substances are generally designated by the General Assembly upon recommendation by the Department. Section 44-53-160(C) provides a process for the Department to expeditiously designate a 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 Chairmen of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee, and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

On March 18, 2022, the United States Food and Drug Administration ("FDA") approved a new drug application ("NDA") for ZTALMY, an oral suspension of ganaxolone, for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder in patients two years of age and older. The Department of Health and Human Services ("HHS") provided the Drug Enforcement Administration ("DEA") with a scheduling recommendation to place ganaxolone and its salts in schedule V of the Controlled Substances Act ("CSA").

In accordance with the CSA, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing ganaxolone, including its salts in schedule V of the CSA. This rule has an effective date of June 1, 2022, *Federal Register*, Volume 87, Number 105, pages 32991-32996; <https://www.govinfo.gov/content/pkg/FR-2022-06-01/pdf/2022-11735.pdf>.

IV. ANALYSIS:

Ganaxolone (3 α -hydroxy-3 β -methyl-5 α -pregnan-20-one) is a new molecular entity with central nervous system activity. Ganaxolone is a neuroactive positive allosteric modulator of gammaaminobutyric acid type-A receptors and an inhibitory neurosteroidal substance that shares structural features and a pharmacological mechanism of action with progesterone and schedule IV depressants alfaxalone and brexanolone.

On March 14, 2022, DEA received from HHS a scientific and medical evaluation entitled “Basis for the Recommendation to Control Ganaxolone and its Salts in Schedule V of the Controlled Substances Act” and a scheduling recommendation. Pursuant to 21 U.S.C. 811(b) and (c), this document contained an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of ganaxolone, along with HHS’s recommendation to control ganaxolone and its salts under schedule V of the CSA.

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 pursuant to 21 U.S.C. 811(c). DEA concluded that ganaxolone meets 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 HHS’ scheduling recommendation, the approval of the NDA by HHS/FDA, and DEA’s determination, DEA is issuing this interim final rule to schedule ganaxolone as a schedule V controlled substance under the CSA.

The CSA lists the findings required to place a drug or other substance in any particular schedule (I, II, III, IV, or V). 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all available data, the Administrator of DEA (“Administrator”), pursuant to 21 U.S.C. 812(b)(4), finds that:

- 1) Ganaxolone has a low potential for abuse relative to the drugs or other substances in schedule IV.
- 2) Ganaxolone has a currently accepted medical use in treatment in the United States.
- 3) Abuse of ganaxolone may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

V. RECOMMENDATION:

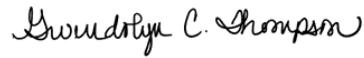
Pursuant to S.C. Code Section 44-53-160(C), the Department recommends placing ganaxolone and its salts in schedule V and the amendment of Section 44-53-270 of the South Carolina Controlled Substances Act to include:

() Ganaxolone (3 α -hydroxy-3 β -methyl-5 α -pregnan-20-one)

Submitted by:



Lisa Thomson
Director, Bureau of Drug Control



Gwen Thompson
Director for Healthcare Quality

Attachment:

Federal Register, Volume 87, Number 105, June 1, 2022

additional 90 days.⁸ On May 10, 2022, the court issued another order to postpone the effective date of the final rule by an additional 90 days.⁹ The court ordered that the new effective date of the final rule is July 8, 2023. Pursuant to the court order, any obligation to comply with a deadline tied to the effective date is similarly postponed, and those obligations and deadlines are now tied to the postponed effective date.

To the extent that 5 U.S.C. 553 applies to this action, the Agency's implementation of this action without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exception in 5 U.S.C. 553(b)(B). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. The 90-day postponement of the effective date, until July 8, 2023, is required by court order in accordance with the court's authority to postpone a rule's effective date pending judicial review (5 U.S.C. 705). Seeking prior public comment on this postponement would have been impracticable, as well as contrary to the public interest in the orderly issuance and implementation of regulations.

Dated: May 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-11568 Filed 5-31-22; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-990]

Schedules of Controlled Substances: Placement of Ganaxolone in Schedule V

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule; request for comments.

SUMMARY: On March 18, 2022, the United States Food and Drug Administration approved a new drug application for ZTALMY, an oral suspension of ganaxolone, for the treatment of seizures associated with cyclin-dependent kinase-like 5

deficiency disorder in patients two years of age and older. The Department of Health and Human Services provided the Drug Enforcement Administration with a scheduling recommendation to place ganaxolone and its salts in schedule V of the Controlled Substances Act. In accordance with the Controlled Substances Act, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, Drug Enforcement Administration is hereby issuing an interim final rule placing ganaxolone, including its salts in schedule V of the Controlled Substances Act.

DATES: This rule is effective June 1, 2022. Comments must be submitted electronically or postmarked on or before July 1, 2022. 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). 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 a hearing or waiver of a hearing in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.44. Requests for a hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before July 1, 2022.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-990" on all correspondence, including any attachments.

- **Electronic comments:** The Drug Enforcement Administration (DEA) 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. 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 electronic submissions 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/DPW, 8701 Morrisette Drive, Springfield, VA 22152.

- **Hearing requests:** All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law asserted in the hearing, must be sent to: Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362-3249.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note, all comments received in response to this docket are considered part of the public record. The Drug Enforcement Administration (DEA) will make comments available, unless reasonable cause is given, 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 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 DEA to make it 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 DEA to make it 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.

DEA will generally make available in publicly redacted form comments

⁸ *R.J. Reynolds Tobacco Co.*, No. 6:20-cv-00176 (E.D. Tex. February 10, 2022) (order postponing effective date), Doc. No. 94.

⁹ *R.J. Reynolds Tobacco Co.*, No. 6:20-cv-00176 (E.D. Tex. May 10, 2022) (order postponing effective date), Doc. No. 96.

containing personal identifying information and confidential business information identified, as directed above. If a comment has so much confidential business information or personal identifying information that DEA cannot effectively redact it, DEA may not make available publicly all or part of that comment. 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 confidential as directed above.

An electronic copy of this document and supplemental information to this interim final rule (IFR) are available at <http://www.regulations.gov> for easy reference.

Request for Hearing or Appearance; Waiver

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 such requests must include a statement of the person’s interests in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. 21 CFR 1316.47(a). 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 hearings and waivers of participation, together with a written statement of position on the matters of fact and law involved in such hearing, must be sent to DEA using the address information provided above.

Background and Legal Authority

Under the Controlled Substances Act (CSA), as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (section 2(b) of Publ. L. 114–89), DEA is required to commence an expedited scheduling action with respect to certain new drugs approved by the 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 (HHS) 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 of HHS 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 (IFR) controlling the drug within 90 days.

Subsection (j)(2) states that the 90-day timeframe starts the later of (1) the date DEA receives HHS’ scientific and medical evaluation/scheduling recommendation, or (2) the date DEA receives notice of the NDA approval by HHS. Subsection (j)(3) specifies that the rulemaking shall become immediately effective as an IFR without requiring DEA to demonstrate good cause therefore. 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.¹

Subsection (j)(3) further provides that the IFR 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 21 U.S.C. 811(b) through (d) and 812(b).

Ganaxolone (3 α -hydroxy-3 β -methyl-5 α -pregnan-20-one) is a new molecular entity (NME) with CNS activity. Ganaxolone is a neuroactive positive allosteric modulator of gamma-aminobutyric acid type-A (GABA-A) receptors and an inhibitory neurosteroidal substance that shares structural features and a pharmacological mechanism of action with progesterone and schedule IV depressants alfaxalone and brexanolone.

On July 20, 2021, Marinus Pharmaceuticals, Inc. (Sponsor) submitted an NDA for ganaxolone to FDA. On March 18, 2022, DEA received notification that FDA, on the same date, approved the NDA for ZTALMY (ganaxolone oral suspension), under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), for the treatment of seizures associated with

¹ 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.

cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients two years of age and older. Pursuant to its FDA-approved prescription drug labeling, ZTALMY is to be administered orally three times daily (TID) with food on a titration schedule through a dose-escalation protocol over the first 3 weeks of drug administration. Patients weighing 28 kg or less receive a final dose of 21 mg/kg TID (63 mg/kg/day) and patients weighing more than 28 kg receive a final dose of 600 mg TID (1800 mg/day).²

Determination To Schedule Ganaxolone

On March 14, 2022, DEA received from HHS a scientific and medical evaluation entitled “Basis for the Recommendation to Control Ganaxolone and its Salts in Schedule V of the Controlled Substances Act” and a scheduling recommendation. Pursuant to 21 U.S.C. 811(b) and (c), this document contained an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of ganaxolone, along with HHS’s recommendation to control ganaxolone and its salts under schedule V of the CSA.

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 pursuant to 21 U.S.C. 811(c). DEA concluded that ganaxolone meets 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 HHS’ scheduling recommendation, the approval of the NDA by HHS/FDA, and DEA’s determination, DEA is issuing this IFR to schedule ganaxolone 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 DEA and HHS analyses are available in their entirety under “Supporting Documents” in the public docket for this IFR at <http://www.regulations.gov>, under Docket Number “DEA–990.” 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

Ganaxolone is an NME that has not been marketed in the United States or

² https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215904s000lbl.pdf. Date accessed March 28, 2022.

any country. Thus, evidence regarding its diversion, illicit manufacturing, or deliberate ingestion is currently lacking. DEA notes that there are no reports of law enforcement encounters of ganaxolone in the National Forensic Laboratory Information System (NFLIS) database,³ which collects drug cases submitted to and analyzed by state and local forensic laboratories. Ganaxolone has sedative effects and is likely to have abuse potential, although less than that of schedule IV sedatives such as lorazepam. Thus, it is reasonable to assume that ganaxolone may be diverted from legitimate channels, used contrary to or without medical advice, and capable of creating hazards to the users and to the safety of the community. In preclinical and clinical studies, ganaxolone produced effects that are less than that of schedule IV sedative drugs such as methohexital and lorazepam. Ganaxolone produced positive subjective responses and euphoria-related adverse events (AEs) that were significantly greater than placebo, but statistically less than that of lorazepam (schedule IV) in healthy humans, nondependent with a history of recreational use of CNS depressants; thus, it is likely to be abused for its sedative effects contrary to medical advice.

2. Scientific Evidence of Its Pharmacological Effects, if Known

Ganaxolone shares a pharmacological profile with other inhibitory neurosteroids such as alfaxalone and brexanolone, both schedule IV drugs. Ganaxolone acts on GABA-A receptors to enhance the effects of GABA, a major inhibitory neurotransmitter in the CNS. Data from *in vitro* binding studies showed that ganaxolone had significant affinity (greater than 96 percent) for the GABA-chloride channels. Ganaxolone did not show significant affinity (less than 50 percent) for 47 other receptor sites, ion channels, steroid sites, and enzymes. The sites tested included abuse-related sites such as dopamine (D₁ and D₂), serotonin (1a, 2a, and 2c), cannabinoid (CB₁ and CB₂), opioid (mu, kappa, delta), glutamate (NMDA/AMPA, phencyclidine, glycine, kainite), and monoamine transporters (dopamine, serotonin, or norepinephrine). Functional activity studies showed that

ganaxolone potentiated GABA-evoked chloride currents in *Xenopus* oocytes expressing human GABA-A receptor subunits.

In animal studies, orally-administered ganaxolone's effect on general behavioral profile showed that it did not produce behavioral activity that differed significantly from the saline-treated group. However, ganaxolone elicited time-dependent (6-hour post treatment) behavior changes such as abnormal gait, grasping loss, abnormal righting reflex, and low carriage indicative of the sedative and muscle relaxation properties of the drug. Ganaxolone's effect on motor coordination was evaluated in three rotarod studies in rats. The studies showed that ganaxolone produced a dose-dependent increase in the number of rats that failed to maintain themselves on the rotarod, indicative of its interference on motor coordination. Ganaxolone produced a dose-dependent decrease in locomotor activity and loss of righting reflex.

In a drug discrimination study using rats trained to discriminate midazolam (schedule IV) and saline, oral doses of ganaxolone (10 and 30 mg/kg) produced full generalization to midazolam stimuli. Ganaxolone's reinforcing properties were assessed by determining whether self-administration behavior was maintained when the drug was substituted for heroin. Data from this study showed that ganaxolone self-administration was much less than that of methohexital (schedule IV) and heroin (schedule I) and was numerically similar to saline. However, ganaxolone at 0.10 mg/kg/injection dose produced self-administration that was statistically significantly greater than saline.

A randomized, double-blind, active- and placebo-controlled, cross-over study was conducted to determine the abuse potential for ganaxolone in healthy, nondependent, recreational CNS depressant users. Oral doses of ganaxolone were compared to an oral dose of lorazepam (schedule IV, served as the positive control). The lower and middle doses of ganaxolone (400 mg and 800 mg, respectively) produced responses within or just outside the acceptable placebo range and were statistically similar to placebo. However, the highest dose of ganaxolone (2000 mg) produced a drug liking score that was significantly different from placebo. The three doses of ganaxolone tested produced drug liking scores that were significantly lower than that of lorazepam. In addition, all three oral doses of ganaxolone (400, 800, and 2000 mg) produced responses on all other positive subjective measures (bipolar visual

analog scale for Overall Drug Liking, High, Good Effects, and Take Drug Again) that were statistically less than those produced by 6 mg oral dose of lorazepam.

In 23 Phase 1 clinical safety studies that were conducted using healthy individuals, eight of the studies showed that ganaxolone produced euphoria-related AEs at all doses tested. Of the eight studies, three were repeat-dose studies and five were acute-dose studies. From the three repeat-dose studies, 24 of 64 subjects who received ganaxolone reported euphoria-related AEs at any dose tested, compared to 0 of 17 subjects who received placebo. Of the five acute-dose studies, euphoria-related AEs were reported by 8 of the 101 subjects who received ganaxolone at any dose tested, compared to 1 of 12 subjects who received placebo. Most of the euphoria-related AEs following ganaxolone administration were mild in severity. In Phase 2/3 clinical studies conducted with ganaxolone in either epilepsy patients or post-traumatic stress disorder patients, the degree of euphoria-related AEs could not be determined because all subjects in these studies were concurrently taking antiepileptic drugs (epilepsy patients) or benzodiazepines (post-traumatic stress disorder patients). Because many antiepileptic drugs and benzodiazepines are known to produce euphoria and sedation, and are often controlled in schedule IV of the CSA, their use in human subjects confounds interpreting any ganaxolone euphoria-related AEs that may be reported during these clinical studies. However, in one of the three clinical studies conducted in patients with migraine, euphoria was reported in 3 of the 163 subjects who received a single 750 mg oral dose of ganaxolone (1.8 percent, 2 moderate, 1 severe), compared to 1 of 164 subjects who received placebo (0.6 percent, 1 mild).

In summary, ganaxolone produced incidence of euphoria-related AEs supportive of its abuse potential. In animal studies, ganaxolone produced interoceptive cues that were similar to those of midazolam, a schedule IV depressant, and these data are consistent with the fact that both drugs share a common mechanism of action involving positive allosteric modulation of the GABA-A receptors. In self-administration studies conducted in animals, ganaxolone produced rewarding effects, but its self-administration was lower than methohexital (schedule IV) and heroin (schedule I) injections. As mentioned by HHS, in clinical studies, ganaxolone produced an 8.8 percent incidence of

³NFLIS is a comprehensive information system that includes data from forensic laboratories that handle more than 96% of an estimated 1.0 million distinct annual State and local drug analysis cases. NFLIS includes drug chemistry results from completed analyses only. While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. See 76 FR 77330, 77332, Dec. 12, 2011. NFLIS data were queried on January 18, 2022.

euphoria-like AEs, including euphoria, thinking abnormal, feeling drunk, and depersonalization, across acute doses of 300 to 1,500 mg/day and repeat doses of 400 to 2,250 mg/day, as compared to that of placebo (2.3 percent) in healthy individuals.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance*

Ganaxolone, chemically known as 3 α -hydroxy-3 β -methyl-5 α -pregnan-20-one, is an NME. It is a structural derivative of allopregnanolone (also known as brexanolone, schedule IV). Ganaxolone is structurally different from brexanolone by the presence of an extra methyl group at the 3 β -position. It is insoluble in water, slightly soluble in methanol, ethanol, isopropanol, ethyl acetate, and toluene (5 to 25 mg/mL at 20 degrees Celsius), and soluble in *N,N*-dimethylacetamide. Ganaxolone is a drug product formulated as a 50 mg/mL white to off-white immediate release oral suspension in water and is administered by mouth TID with food. Ganaxolone is absorbed with a time to peak plasma concentration of 2.0 to 3.0 hours following oral administration. It undergoes first pass metabolism following oral administration with 10 percent bioavailability. It is approximately 99 percent protein bound in serum and has a terminal half-life at steady state of about 8–10 hours.

As discussed in the background section, ganaxolone has an accepted medical use in the United States.

4. *Its History and Current Pattern of Abuse*

There is no information on the history and current pattern of abuse for ganaxolone, since it has not been marketed, legally or illegally, in the United States or any other country. There is no evidence of diversion of ganaxolone that has been distributed for research, such as for clinical trials. Data from preclinical and clinical studies indicate that the abuse potential of ganaxolone is less than that of schedule IV CNS depressants such as methohexital and lorazepam. Consistent with the fact that ganaxolone is an NME, the NFLIS database had no records of encounters by law enforcement.

In summary, pharmacological data on ganaxolone show that it produces abuse-related AEs and has an abuse potential less than that of schedule IV CNS depressants.

5. *The Scope, Duration, and Significance of Abuse*

Data from preclinical and clinical studies showed that ganaxolone has an

abuse potential that is less than that of schedule IV depressants. Thus, ganaxolone has a low potential for abuse relative to substances in schedule IV. A search by DEA of the NFLIS database found no evidence of law enforcement encounters of ganaxolone in the United States. Because ganaxolone is a positive allosteric modulator of GABA-A receptors and has abuse potential, upon availability of ganaxolone in the market, it is likely to be abused.

6. *What, if any, Risk There Is to the Public Health*

Ganaxolone's abuse potential, although less than that of schedule IV depressants, is an indication of its public health risk. As such, upon availability for marketing, it is likely to pose risk to public health comparable to drugs in schedule V. According to information mentioned in the prescription product label for ZTALMY (ganaxolone), concomitant use of opioids, antidepressants, or other CNS depressants such as alcohol may potentiate incidence of somnolence and sedation in patients receiving ganaxolone. The abuse of ganaxolone may present risks to the public health at a level similar to those associated with the abuse of CNS depressants.

7. *Its Psychic or Physiological Dependence Liability*

Ganaxolone's psychic and physiological dependence liability was assessed using data from a rat physical dependence study and human data. A physical dependence study was not conducted in clinical studies because abrupt discontinuation of an antiepileptic drug in epileptic patients presents serious safety concerns. As described by HHS, data from a physiologic dependence study conducted in rats demonstrated that chronic administration of ganaxolone produced a decrease in body weight and changes in behavior that included ataxia, rearing, escape attempts from the cage, increased body tone, increased locomotor activity, increased reaction to sound, explosive movements, and piloerection. Decreases in body weight, food and water intake, and increased body temperature were observed upon discontinuation of ganaxolone. During ganaxolone discontinuation, 5 of 10 rats showed behaviors that included increased locomotor activity, increased reaction to sound, hunched posture, and piloerection. Further, since ganaxolone produced positive subjective responses and euphoria-related AEs in human subjects, it is likely that it may produce psychic dependence.

In summary, data from animal studies demonstrate that chronic administration of ganaxolone produces signs or symptoms of withdrawal upon discontinuation. Ganaxolone produces physical dependence.

8. *Whether the Substance Is an Immediate Precursor of a Substance Already Controlled Under the CSA*

Ganaxolone is not an immediate precursor of any controlled substance, as defined by 21 U.S.C. 802(23).

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

Determination of Appropriate Schedule

The CSA lists the findings required to place a drug or other substance in any particular schedule (I, II, III, IV, or V). 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all available data, the Administrator of DEA (Administrator), pursuant to 21 U.S.C. 812(b)(5), finds that:

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

Ganaxolone, a neuroactive steroid, is a positive allosteric modulator of GABA-A receptors and produces sedation in general behavioral studies including rotarod and locomotion studies. In a drug discrimination study in animals, ganaxolone generalized to midazolam (schedule IV), demonstrating it has GABA-A receptor agonist properties. In a self-administration study in animals, ganaxolone self-administration was significantly different from saline, but was less than that of methohexital (schedule IV) and heroin (schedule I). Ganaxolone produced positive subjective responses and euphoria-related AEs less than that of lorazepam (schedule IV), but greater than that of placebo in a human abuse potential study. Furthermore, data from pharmacokinetic clinical studies show that ganaxolone produced incidence of euphoria in 8.8 percent of healthy individuals as compared to 2.3 percent incidence following placebo. Therefore, ganaxolone has some potential for abuse, but it is low relative to lorazepam, methohexital and other substances in schedule IV.

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

FDA recently approved the NDA for ZTALMY (ganaxolone) as an oral adjunctive therapy for the treatment of an epilepsy condition, cyclin-dependent, kinase-like 5 deficiency disorder, in patients aged two years and older. Thus, ganaxolone has a currently accepted medical use in treatment in the United States.

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

Ganaxolone shares a similar pharmacology profile with brexanolone (schedule IV). Data from a rat physical dependence study demonstrated that discontinuation of chronic administration of ganaxolone produced withdrawal syndrome. Thus, abuse of ganaxolone may lead to limited physical dependence. Further, because ganaxolone produced positive subjective responses and euphoria-related AEs, it may produce psychic dependence. However, there were fewer reports of euphoria-related AEs associated with ganaxolone than lorazepam (schedule IV). Ganaxolone may lead to limited physical or psychological dependence relative to other substances in schedule IV.

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

Requirements for Handling Ganaxolone

Ganaxolone 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), or who desires to handle, ganaxolone must be registered with 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 ganaxolone and is not registered with DEA must submit an application for registration and may not continue to handle ganaxolone unless DEA has approved that application,

pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. These registration requirements, however, are not applicable to patients (end users) who possess ganaxolone pursuant to a lawful prescription.

2. *Disposal of stocks.* Any person unwilling or unable to obtain a schedule V registration to handle ganaxolone, but who subsequently does not desire or is not able to maintain such registration must surrender all quantities of currently held ganaxolone, or may transfer all quantities of currently held ganaxolone to a person registered with DEA. Ganaxolone is required to be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, state, local, and tribal laws.

3. *Security.* Ganaxolone is subject to schedule III–V security requirements for DEA registrants, and it must be handled and stored in accordance with 21 CFR 1301.71–1301.77. Non-practitioners handling ganaxolone must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93. These requirements, however, are not applicable to patients (end users) who possess ganaxolone pursuant to a lawful prescription.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of ganaxolone 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 ganaxolone must take an inventory of ganaxolone on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who registers with DEA to handle ganaxolone must take an initial inventory of all stocks of controlled substances (including ganaxolone) 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(a) and (b).

After the initial inventory, every DEA registrant must take an inventory of all stocks of controlled substances (including ganaxolone) 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. These requirements, however, are not applicable to patients (end users) who possess ganaxolone pursuant to a lawful prescription.

6. *Records and Reports.* DEA registrants must maintain records and submit reports for ganaxolone, pursuant

to 21 U.S.C. 827, 832(a), and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317.

7. *Prescriptions.* All prescriptions for ganaxolone, or products containing ganaxolone, 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 ganaxolone may only be for the legitimate purposes consistent with the drug's labeling, or for research activities authorized by the FDCA, as applicable, and the CSA.

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

10. *Liability.* Any activity involving ganaxolone 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 APA (5 U.S.C. 553) generally requires notice and comment for rulemakings. However, 21 U.S.C. 811(j) provides that in cases where a certain new drug is (1) approved by HHS, under section 505(c) of the FDCA and (2) HHS recommends control in CSA schedule II–V, DEA shall issue an IFR scheduling the drug within 90 days. As stated in the legal authority section, the 90-day time frame is the later of: (1) The date DEA receives HHS's scientific and medical evaluation/scheduling recommendation, or (2) the date DEA receives notice of the NDA approval by HHS. Additionally, subsection (j) specifies that the rulemaking shall become immediately effective as an IFR without requiring DEA to demonstrate good cause.

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

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 (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 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 E.O. 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 E.O. 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. As noted in the above discussion regarding the applicability of the APA, DEA is not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply to this IFR.

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 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.

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. However, pursuant to the CRA, DEA is submitting a copy of this IFR 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), 956(b) unless otherwise noted.

■ 2. In § 1308.15:

■ a. Redesignate paragraphs (e)(4) through (6) as paragraphs (e)(5) through (7); and

■ b. Add new paragraph (e)(4).

The addition reads as follows:

§ 1308.15 Schedule V.

* * * * *
(e) * * *

(4) Ganaxolone (3α-hydroxy-3β-methyl-5α-pregnan-20-one) 2401

* * * * *

Anne Milgram,

Administrator.

[FR Doc. 2022–11735 Filed 5–31–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–495]

Schedules of Controlled Substances: Placement of N-Ethylhexedrone, alpha-Pyrrolidinohexanophenone, 4-Methyl-alpha-ethylaminopentiofenone, 4'-Methyl-alpha-pyrrolidinoheptiofenone, alpha-Pyrrolidinoheptaphenone, and 4'-Chloro-alpha-pyrrolidinovalerophenone in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: By this rule, the Drug Enforcement Administration permanently places six synthetic cathinones, as identified in this rule, in

schedule I of the Controlled Substances Act. These six substances are currently listed in schedule I pursuant to a temporary scheduling order. As a result of this rule, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess) or propose to handle these six specified controlled substances will continue to apply.

DATES: Effective June 1, 2022.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–8207.

SUPPLEMENTARY INFORMATION: In this rule, the Drug Enforcement Administration (DEA) is permanently

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

June 29, 2022

(X) ACTION/DECISION

() INFORMATION

I. TITLE: Request for Placement of Methoxetamine in Schedule I for Controlled Substances in South Carolina

II. SUBJECT: Placement of Methoxetamine in Schedule I for Controlled Substances

III. FACTS:

Controlled substances are governed by the South Carolina Controlled Substances Act, Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule I substances are listed in Section 44-53-190 of the South Carolina Code of Laws. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances shall be made," controlled substances are generally designated by the General Assembly upon recommendation by the Department. Section 44-53-160(C) provides a process for the Department to expeditiously designate a 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 Chairmen of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee, and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

On June 6, 2022, the Administrator of the Drug Enforcement Administration ("DEA") issued a final rule placing 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one (methoxetamine, MXE), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, in schedule I of the Controlled Substances Act ("CSA") to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose

to handle, methoxetamine. This final rule was published on June 6, 2022, with an effective date of July 6, 2022, *Federal Register*, Volume 87, Number 108, pages 34166-34169; <https://www.govinfo.gov/content/pkg/FR-2022-06-06/pdf/2022-11933.pdf>.

IV. ANALYSIS:

Methoxetamine, also known as 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one or 2-(3-methoxyphenyl)-2-(N-ethylamino)cyclohexanone or MXE, belongs to the arylcyclohexylamine class of drugs with dissociative anesthetic and hallucinogenic properties, similar to phencyclidine (PCP), a schedule II controlled substance, and ketamine, a schedule III controlled substance. Methoxetamine has no approved medical use in the United States. In March 2016, the Commission on Narcotic Drugs (“CND”) voted to place methoxetamine in Schedule II of the 1971 Convention (CND Dec/59/6) during its 59th Session due to its dependence and abuse potential.

On April 14, 2018, in accordance with 21 U.S.C. 811(b), and in response to DEA’s December 30, 2014, request and April 14, 2017, submission of additional data, the Department of Health and Human Services (“HHS”) provided to DEA a scientific and medical evaluation and scheduling recommendation for methoxetamine. DEA reviewed the scientific and medical evaluation and scheduling recommendation for schedule I placement provided by HHS, and all other relevant data, pursuant to 21 U.S.C. 811(b) and (c), and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 811(b)(1), that this substance warrants control in schedule I.

After consideration of the public comment, scientific and medical evaluation, and accompanying recommendation of HHS, and after its own eight-factor evaluation, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of methoxetamine. DEA is permanently scheduling methoxetamine as a controlled substance under the CSA.

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also specifies the findings required to place a drug or other substance in any particular schedule, 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Acting Assistant Secretary for Health of HHS and review of all other available data, the Administrator of DEA, pursuant to 21 U.S.C. 812(b)(1), finds that:

- 1) Methoxetamine has a high potential for abuse that is comparable to other scheduled substances such as the ethylamine analog of phencyclidine (PCE; schedule I), the thiophene analog of phencyclidine (TCP; schedule I), phencyclidine (PCP; schedule II), and ketamine (schedule III).
- 2) Methoxetamine has no currently accepted medical use in treatment in the United States.
- 3) There is a lack of accepted safety for use of methoxetamine under medical supervision. Because methoxetamine has no approved medical use and has not been investigated as a new drug, its safety for use under medical supervision has not been determined. Therefore, there is a lack of accepted safety for use of methoxetamine under medical supervision.

V. RECOMMENDATION:

Pursuant to S.C. Code Section 44-53-160(C), the Department recommends placing Methoxetamine in Schedule I in the same manner as the federal Drug Enforcement Administration. The listing includes its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is

possible within the specific chemical designation, to schedule I for controlled substances in South Carolina and the amendment of Section 44-53-190 of the South Carolina Controlled Substances Act to include:

() 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one (methoxetamine, MXE)

Submitted by:



Lisa Thomson
Director, Bureau of Drug Control



Gwen Thompson
Director for Healthcare Quality

Attachment:

Federal Register, Volume 87, Number 108, June 6, 2022

thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY—UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 876.5026 to subpart F to read as follows:

§ 876.5026 Non-implanted electrical stimulation device for management of premature ejaculation.

(a) *Identification.* A non-implanted electrical stimulation device for management of premature ejaculation is intended to be used in patients with premature ejaculation by delivery of electrical stimulation to the perineal muscles and nerves.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The device must be demonstrated to be biocompatible.

(2) Performance testing must demonstrate the electromagnetic compatibility, electrical safety, and thermal safety of the device.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Mechanical performance;
(ii) Electrical stimulation parameters;
and

(iii) Battery performance.

(4) Performance testing must support shelf life by demonstrating continued device functionality over the identified shelf life.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Labeling must include:

(i) Specific instructions regarding safe placement and correct use of the device;
(ii) Warning(s) against use by patients with active implanted medical devices;
and

(iii) A shelf life.

Dated: May 26, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–12082 Filed 6–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–568]

Schedules of Controlled Substances: Placement of Methoxetamine (MXE) in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one (methoxetamine, MXE), including its salts, isomers, and salts of isomers

whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, in schedule I of the Controlled Substances Act to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle, methoxetamine.

DATES: Effective July 6, 2022.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), February 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2)–(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention indicating that a drug or other substance has been added to a specific schedule, the Secretary of the Department Health and Human Services (HHS),¹ after consultation with the Attorney General, shall determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.² In the event that the Secretary of HHS did not consult with the Attorney General, and

¹ As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the Controlled Substances Act, with the concurrence of NIDA. 50 FR 9518 (March 8, 1985). The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

² 21 U.S.C. 811(d)(3).

the Attorney General did not issue a temporary order, as provided under 21 U.S.C. 811(d)(4), the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) control. Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, schedule or transfer between any schedules any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes the findings prescribed by 21 U.S.C. 812(b) to schedule the drug or other substance. The Attorney General has delegated this scheduling authority to the Administrator of the Drug Enforcement Administration (DEA).³

Background

Methoxetamine, also known as 2-(ethylamino)-2-(3-(3-methoxyphenyl)cyclohexan-1-one or 2-(3-methoxyphenyl)-2-(N-ethylamino)cyclohexanone or MXE, belongs to the arylcyclohexylamine class of drugs with dissociative anesthetic and hallucinogenic properties, similar to phencyclidine (PCP), a schedule II controlled substance, and ketamine, a schedule III controlled substance. Methoxetamine has no approved medical use in the United States. In March 2016, the Commission on Narcotic Drugs (CND) voted to place methoxetamine in Schedule II of the 1971 Convention (CND Dec/59/6) during its 59th Session due to its dependence and abuse potential.

DEA and HHS Eight Factor Analyses

On April 14, 2018, in accordance with 21 U.S.C. 811(b), and in response to DEA's December 30, 2014, request and April 14, 2017, submission of additional data, HHS provided to DEA a scientific and medical evaluation and scheduling recommendation for methoxetamine. DEA reviewed the scientific and medical evaluation and scheduling recommendation for schedule I placement provided by HHS, and all other relevant data, pursuant to 21 U.S.C. 811(b) and (c), and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 811(b)(1), that this substance warrants control in schedule I. Both DEA and HHS Eight-Factor analyses are available in their entirety under the tab Supporting Documents of the public docket for this action at <https://www.regulations.gov> under docket number DEA-568.

Notice of Proposed Rulemaking To Schedule Methoxetamine

On December 7, 2021 (86 FR 69187), DEA published a notice of proposed rulemaking (NPRM) to permanently control methoxetamine in schedule I. Specifically, DEA proposed to add methoxetamine to the hallucinogenic substances list under 21 CFR 1308.11(d). The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before February 7, 2022. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on or before February 7, 2022.

Comments Received

DEA received one comment that recognized the dangers and public health risks, and fully supported the placement of methoxetamine in schedule I.

DEA Response: DEA appreciates this comment in support of this rulemaking.

Scheduling Conclusion

After consideration of the public comment, scientific and medical evaluation and accompanying recommendation of HHS, and after its own eight-factor evaluation, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of methoxetamine. DEA is permanently scheduling methoxetamine as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also specifies the findings required to place a drug or other substance in any particular schedule, 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Acting Assistant Secretary for Health of HHS and review of all other available data, the Administrator of DEA, pursuant to 21 U.S.C. 812(b)(1), finds that:

(1) Methoxetamine has a high potential for abuse that is comparable to other scheduled substances such as the ethylamine analog of phencyclidine (PCE; schedule I), the thiophene analog of phencyclidine (TCP; schedule I), phencyclidine (PCP; schedule II), and ketamine (schedule III);

(2) Methoxetamine has no currently accepted medical use in treatment in the United States. There are no approved New Drug Applications for methoxetamine and no known therapeutic applications for methoxetamine in the United States.

Therefore, methoxetamine has no currently accepted medical use in treatment in the United States.⁴

(3) There is a lack of accepted safety for use of methoxetamine under medical supervision. Because methoxetamine has no approved medical use and has not been investigated as a new drug, its safety for use under medical supervision has not been determined. Therefore, there is a lack of accepted safety for use of methoxetamine under medical supervision.

Based on these findings, the Administrator of DEA concludes that methoxetamine as well as its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible warrants control in schedule I of the CSA.⁵

Requirements for Handling Methoxetamine

Methoxetamine is subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, import, export, engagement in research, conduct instructional activities or chemical analysis with, and possession of schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, methoxetamine must be registered with 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 methoxetamine and is not registered with DEA must submit an application for registration and may not continue to handle methoxetamine, unless DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312.

⁴ Although there is no evidence suggesting that methoxetamine has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: i. The drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. 57 FR 10499 (1992), *pet. for rev. denied*, *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

⁵ 21 U.S.C. 812(b)(1).

³ 28 CFR 0.100.

2. *Disposal of stocks.* Any person unwilling or unable to obtain a schedule I registration must surrender or transfer all quantities of currently held methoxetamine to a person registered with DEA before the effective date of a final scheduling action in accordance with all applicable Federal, State, local, and tribal laws. Methoxetamine must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Methoxetamine is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.71–1301.76, as of the effective date of this final scheduling action. Non-practitioners handling methoxetamine must comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

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

5. *Quota.* Only registered manufacturers are permitted to manufacture methoxetamine in accordance with a quota assigned pursuant to 21 U.S.C. 826, and in accordance with 21 CFR part 1303.

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

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

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

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports for methoxetamine, or products containing methoxetamine, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312 and 1317. Manufacturers and distributors must submit reports regarding methoxetamine to the Automation of Reports and Consolidated Order System pursuant to

21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes methoxetamine must comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

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

10. *Liability.* Any activity involving methoxetamine 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

Executive Orders 12866 and 13563 (Regulatory Planning and Review; Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a), this final 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 pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 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 E.O. 13132. The proposed 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 E.O. 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.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995.⁶

Regulatory Flexibility Act

The Administrator of DEA, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this final rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA is placing the substance methoxetamine (chemical name: 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, in schedule I of the CSA to enable the United States to meet its obligations under the 1971 Convention. This action imposes the regulatory controls and administrative, civil, and/or criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle methoxetamine.

Based on the review of HHS’s scientific and medical evaluation and all other relevant data, DEA determined that methoxetamine has high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use under medical supervision. DEA’s research confirms that there is no legitimate commercial market for methoxetamine in the United States. Therefore, this final rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the “Regulatory Flexibility Act” section above, DEA has determined pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.*) that this final rule 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

⁶ 44 U.S.C. 3501–3521.

annually for inflation) in any 1 year * * *.” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of the 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, 21 CFR part 1308 is amended 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), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraph (d)(100) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(100) 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one (methoxetamine, MXE) 7286

* * * * *

Anne Milgram,

Administrator.

[FR Doc. 2022-11933 Filed 6-3-22; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 587

Publication of Russian Harmful Foreign Activities Sanctions Regulations Web General Licenses 25A, 33, 34, and 35

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of Web General Licenses.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing four general licenses (GLs) issued pursuant to the Russian Harmful Foreign Activities Sanctions Regulations: GL 25A, GL 33, GL 34, and GL 35, each of which was previously issued on OFAC's website.

DATES: GL 25A, GL 33, GL 34, and GL 35 were each issued on May 8, 2022. See **SUPPLEMENTARY INFORMATION** of this publication for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202-622-2480; Assistant Director for Regulatory Affairs, 202-622-4855; or Assistant Director for Sanctions Compliance & Evaluation, 202-622-2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are

available on OFAC's website: www.treas.gov/ofac.

Background

OFAC issued GL 25A, GL 33, GL 34, and GL 35 on May 8, 2022 on its website to authorize certain transactions otherwise prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587. GL 25A does not contain an expiration date. GL 33 expires at 12:01 a.m. eastern daylight time, June 7, 2022. GL 34 expires at 12:01 a.m. eastern daylight time, July 7, 2022. GL 35 expires at 12:01 a.m. eastern daylight time, August 20, 2022. The texts of GLs 25A, 33, 34, and 35 are provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations 31 CFR Part 587

GENERAL LICENSE NO. 25A

Authorizing Transactions Related to Telecommunications and Certain Internet-Based Communications

(a) Except as provided in paragraph (c) of this general license, all transactions ordinarily incident and necessary to the receipt or transmission of telecommunications involving the Russian Federation that are prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR), are authorized.

(b) Except as provided in paragraph (c) of this general license, the exportation or reexportation, sale, or supply, directly or indirectly, from the United States or by U.S. persons, wherever located, to the Russian Federation of services, software, hardware, or technology incident to the exchange of communications over the internet, such as instant messaging, videoconferencing, chat and email, social networking, sharing of photos, movies, and documents, web browsing,

blogging, web hosting, and domain name registration services, that is prohibited by the RuHSR, is authorized.

(c) This general license does not authorize:

(1) The opening or maintaining of a correspondent account or payable-through account for or on behalf of any entity subject to Directive 2 under Executive Order (E.O.) 14024, *Prohibitions Related to Correspondent or Payable-Through Accounts and Processing of Transactions Involving Certain Foreign Financial Institutions*;

(2) Any debit to an account on the books of a U.S. financial institution of the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, or the Ministry of Finance of the Russian Federation;

(3) Any transactions prohibited by E.O. 14066 or E.O. 14068; or

(4) Any transactions involving Joint Stock Company Channel One Russia, Joint Stock Company NTV Broadcasting Company, or Television Station Russia-1, unless separately authorized.

(d) Effective May 8, 2022, General License No. 25, dated April 7, 2022, is replaced and superseded in its entirety by this General License No. 25A.

Note to General License No. 25A. Nothing in this general license relieves any person from compliance with any other Federal laws or requirements of other Federal agencies, including export, reexport, and transfer (in-country) licensing requirements maintained by the Department of Commerce's Bureau of Industry and Security under the Export Administration Regulations, 15 CFR parts 730-774.

Andrea M. Gacki

Director, Office of Foreign Assets Control

Dated: May 8, 2022