SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

May 5, 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 March 1, 2022, through March 31, 2022.

III. **FACTS:** For the period of March 1, 2022, through March 31, 2022, Healthcare Quality reports five (5) Consent Orders totaling $61,400 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)	0	5	$61,400	$38,000
TOTAL		**0**	**5**	**$61,400**	**$38,000**

Submitted By:

Gwendolyn C. Thompson

Gwen C. Thompson
Deputy Director
Healthcare Quality

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

May 5, 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. Pacifica Senior Living Skylyn – Spartanburg, SC

Inspections and Investigations: The Department conducted complaint investigations in February 2021 March 2021, April 2021, three investigations in October 2021, a routine inspection in November 2021; and a fire and life safety inspection in 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 documented monthly resident notes of observation. The Department further found the facility failed to:

- Properly initial medication administration records ("MARs") as medications were administered, a repeat violation.
- Ensure all medications were kept in the original containers or packaging.
- Ensure medications were secure and inaccessible in a resident's room, a repeat violation.
- Supply a written fire plan and evacuation plan.
- Maintain fire protection and suppression systems in accordance with the codes adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.
- Maintain records of fire drills at the facility.
- Evacuate residents to the outside of the building to a selected assembly point during fire drills.
- Maintain all equipment and building components in good repair and operating condition and by failing to comply with codes adopted by the Building Codes Council and the South Carolina State Fire Marshal applicable to CRCFs, for a third occurrence.
- Ensure that the facility was free from vermin, a fifth occurrence.
- Ensure each specific interior area of the facility was clean, a repeat violation.
- Ensure that soiled linen/clothing were kept in enclosed/covered containers.
- Ensure that safety precautions are taken against fire and other hazards when oxygen is dispensed, administered, or stored.
- Ensure that portable electric or unvented fuel heaters were not permitted in the facility and by failing to comply with codes officially adopted by the Building Codes Council and the South Carolina State Fire Marshal applicable to CRCFs, a repeat violation.
- Ensure that all emergency electrical services were properly illuminated and by failing to comply with codes officially adopted by the South Carolina State Fire Marshal applicable to CRCFs.

Moreover, the facility failed to ensure that the HVAC system was inspected at least once a year by a certified/licensed technician.

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 $14,000 against the facility. The facility was required to pay $10,000 of the assessed monetary penalty within thirty (30) days after the execution of the Consent Order. The remaining $4,000 will be held in abeyance upon a six-month substantial compliance period. The facility also agreed to schedule and attend a compliance assistance meeting with the Department within forty-five (45) days of executing the Consent Order.

Remedial Action: The facility has made the required payment, in full, totaling $10,000. The compliance assistance meeting was held April 12, 2022.

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

2. J&T Residential Care Facility – Hampton, SC

Inspections and Investigations: The Department conducted a fire and life safety investigation in March 2022 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 comply with the codes adopted by the SC Building Codes Council and State Fire Marshal. Specifically, there were multiple electrical hazards in the wiring of the breaker panel, and the electrical wiring was modified and constituted an electrical shock or fire hazard. The facility was acquiring power from a source away from the building.

Enforcement Action: The parties agreed to resolve the matter with a consent order. The parties executed a consent order agreeing to an immediate suspension of the facility's license. The facility's license will be suspended until the following conditions are met:

- The facility will have an licensed electrician inspect its electrical system and issue an written report that details any necessary repairs to ensure a safe electrical system.
- The facility will send the report from the electrician, as well as the electrician's credentials, to the Department.
- The facility will complete the necessary repairs, as described in the reports, if any. To the extent repairs are required, the facility understands and agrees to notify and coordinate with the Department, as required by statute and regulation.

Upon completion of the repairs and any construction requirements, the Department will conduct an inspection. When the Department determines the facility is in substantial compliance with the regulation, the Department will issue a letter lifting the suspension. The facility is also required to provide the Department with weekly e-mail updates until the Department determines that the updates are no longer required.

Remedial Action: The six (6) residents were relocated on March 17, 2022. The facility has been sending the required weekly updates. The facility submitted reports from the electrician to the Department. The Department conducted a fire and life safety inspection on April 20, 2022, and a construction project inspection on April 20, 2022. The facility has not completed all required repairs.

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

3. Midway Residential Care Facility #4 – Moore, SC

Inspections and Investigations: The Department conducted an investigation and routine inspection in March 2021 and routine follow-up inspections in 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 ensure the facility was free of vermin.

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 $3,000 assessed monetary penalty within thirty (30) days after the execution of the Consent Order. The facility also agreed to schedule and attend a compliance assistance meeting with the Department within forty-five (45) days of executing the Consent Order.

Remedial Action: The facility has made the required payment, in full, totaling $3,000. The compliance assistance meeting is scheduled April 26, 2022.

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

4. Carriage House Senior Living of Sumter – Sumter, SC

Inspections and Investigations: The Department conducted an investigation and routine inspection in February 2021, an investigation in September 2021, and a routine follow-up inspection in October 2021, and found the facility in violation of 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 resident's individual care plan (ICP), by not developing and signing the ICP within seven (7) days of admission, not reviewing and/or revising the ICP at least semi-annually, and not dating the ICP.
- Maintain all equipment and building components in good repair and operating condition.
- Promote conditions that prevent the spread of infections, contagious and/or communicable diseases in compliance with guidelines from the Centers for Disease Control and Prevention.
- Ensure the facility was free of vermin and/or offensive odors.
- Ensure that each specific area of the facility was cleaned.

Moreover, the facility failed to ensure that harmful chemicals in the interior of the facility are stored safely and inaccessible to residents and to keep the facility grounds free of rubbish.

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 facility. The facility was required to pay the $5,000 assessed monetary penalty within forty-five (45) days after the execution of the Consent Order. The facility also agreed to schedule and attend a compliance assistance meeting with the Department within forty-five (45) days of executing the Consent Order.

Remedial Actions: The facility has made the required payment, in full, totaling $5,000. The compliance assistance meeting was held March 30, 2022.

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

5. Carriage House Senior Living of Florence – Florence, SC

Inspections and Investigations: The Department conducted a fire and life safety inspection in January 2021, complaint investigations in April 2021, May 2021, June 2021, July 2021, and October 2021, routine inspections in February 2021 and August 2021, and follow-up inspections in June 2021, July 2021, August 2021, and September 2021, and found the facility in violation of regulatory requirements.

Violations: The Department found the facility violated Regulation 61-84, *Standards for Licensing Community Residential Care Facilities*, by:

- Failing to allow individuals authorized by S.C. Code of Laws access to all areas and records in a timely manner.
- Failing to have a licensed administrator.
- Failing to have sufficient staff members/direct care volunteers on duty during peak hours.
- Failing to notify the department within seventy-two (72) hours of a change in its administrator status.
- Failing to have monthly notes of observation for residents.
- Failing to have Individual Care Plan (IPC) for a resident and by failing to ensure a resident's ICP was reviewed and/or revised at least simi-annually.
- Failing to maintain resident financial records at the facility.
- Failing to complete a physical examination on residents prior to admission and annually thereafter.
- Failing to ensure there were documented reviews of Medication Administration Records (MARs) at each shift change by outgoing staff with incoming staff.
- Failing to keep medications in their original containers.
- Failing to ensure there were documented reviews of control sheets at each shift change by outgoing staff with incoming staff.
- Storing medications in residents' rooms without authorization in writing to self-administer by a physician or other authorized healthcare provider.
- Failing to maintain its kitchen in compliance with Regulation 61-25, *Retail Food Establishment*.
- Failing to keep all equipment and building components in good repair and operating condition and failing to comply with to comply with the codes adopted by the Building Codes Council and the State Fire Marshal applicable to CRCFs.
- Failing to 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).
- Failing to ensure the facility was free of vermin and/or offensive odors.
- Failing to ensure each specific interior area of the facility was clean.
- Failing to ensure safe storage of chemicals, cleaning materials, and supplies, which are indicated as harmful on the product label.
- Failing to take safety precautions where oxygen and concentrators are stored by not posting "No Smoking" signs conspicuously.
- Allowing smoking in a resident's room.

Moreover, the facility failed to maintain hot water temperature accessible to residents to at least 100°F in residents' bathrooms and failed to have covered receptacles in the women's bathroom.

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 $39,400 against the facility. The facility was required to pay the $20,000 of assessed monetary penalty in four installments of $5,000. The first payment will be due 45 days, the second payment will be due 90 days, the third payment will be due 135 days, and the fourth payment will be due 180 days after execution of this Consent Order. The remaining $19,400 of the assessed monetary penalty will be stayed upon a six-month period of substantial compliance. The facility agreed to a suspension of admission of new residents. The suspension of admission of new residents will be held in abeyance for a six-month period of substantial compliance as determined by the Department. If during the six-month period the Department finds the facility to be in substantial non-compliance the Consent Order, the Department may call-in all or a portion of the remaining balance of the $39,400 civil penalty. If during the six-month period after the Department finds the facility to be in substantial non-compliance, the Department may call-in the suspension of admission of new residents. The suspension will be immediately implemented by the facility upon receipt of written notice of the Department's call-in. Further, the suspension will remain in effect until the Department determines the facility has remedied the violations and provides written notice of such determination. The facility agrees to schedule and attend a compliance assistance meeting with representatives of the Department within 45 days of the execution of this Consent Order.

Remedial Actions: The facility made the first required payment, totaling $5,000. The compliance assistance meeting was held March 31, 2022.

Prior Actions: In November 2020, the parties executed an expedited consent order imposing a civil monetary penalty of $5,000 for failing to promote conditions to 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) and provide for the proper disposal of toxic and hazardous substances. The facility made the required payment, in full, totaling $5,000.

SUMMARY SHEET
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
May 5, 2022

_____ ACTION/DECISION

__X__ INFORMATION

1. **TITLE:** Administrative and Consent Orders issued by the Office of Environmental Affairs.

1. **SUBJECT:** Administrative and Consent Orders issued by the Office of Environmental Affairs during the period March 1, 2022, through March 31, 2022.

1. **FACTS:** For the reporting period of March 1, 2022, through March 31, 2022, the Office of Environmental Affairs issued forty-four (44) Consent Orders with total assessed civil penalties in the amount of two hundred seventy-one thousand, nine hundred twenty dollars ($271,920.00). Also, ten (10) Administrative Orders with total assessed civil penalties in the amount of ninety-three thousand, two hundred dollars ($93,200.00) were reported during this period.

Bureau and Program Area	Administrative Orders	Assessed Penalties	Consent Orders	Assessed Penalties
Land and Waste Management				
UST Program	4	$68,700.00	8	$28,280.00
Aboveground Tanks	0	0	0	0
Solid Waste	1	$3,500.00	1	$600.00
Hazardous Waste	0	0	1	$35,000.00
Infectious Waste	0	0	4	$143,400.00
Mining	0	0	1	$1,000.00
SUBTOTAL	**5**	**$72,200.00**	**15**	**$208,280.00**
Water				
Recreational Water	0	0	0	0
Drinking Water	0	0	7	$16,140.00
Water Pollution	0	0	7	$21,800.00
Dam Safety	0	0	0	0
SUBTOTAL	**0**	**0**	**14**	**$37,940.00**
Air Quality				
SUBTOTAL	**3**	**$21,000.00**	**3**	**$14,000.00**
Environmental Health Services				
Food Safety	0	0	11	$10,700.00
Onsite Wastewater	2	0	1	$1,000.00
SUBTOTAL	**2**	**0**	**12**	**$11,700.00**
OCRM				
SUBTOTAL	**0**	**0**	**0**	**0**
TOTAL	**10**	**$93,200.00**	**44**	**$271,920.00**

Submitted by:

Myra C. Reece
Director of Environmental Affairs

ENVIRONMENTAL AFFAIRS ENFORCEMENT REPORT
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
May 5, 2022

BUREAU OF LAND AND WASTE MANAGEMENT

Underground Storage Tank Enforcement

1) Order Type and Number: Administrative Order 21-0615-UST
Order Date: February 15, 2021
Individual/Entity: **Bhole Baba, LLC**
Facility: Swami Food Store
Location: 830 Bleckley Street
Anderson, SC 29625
Mailing Address: Same
County: Anderson
Previous Orders: None
Permit/ID Number: 00565
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(b)(1), 280.34(c), 280.70(a), 280.93(a) and 280.110(c) (2012 & Supp 2020).

Summary: Bhole Baba, LLC (Individual/Entity) owns and operates underground storage tanks in Anderson County, South Carolina. The Department issued a Transfer of Ownership – New Owner letter on June 7, 2021. A Notice of Alleged Violation (NOAV) dated October 5, 2020, was enclosed. Additional NOAVs were issued on July 17, 2021, and October 6, 2021. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to have corrosion protection system tested at least once every three (3) years; failed to provide records to the Department upon request; failed to continue operation and maintenance of corrosion protection on a temporarily closed UST; failed to demonstrate financial responsibility for an UST system; and, failed to submit evidence of financial assurance.

Action: The Individual/Entity is required to submit: a completed Tank and Sludge Disposal Form for the permanent closure of the USTs at the Facility and within sixty (60) days of the Department's approval of the form, permanently close the USTs and submit an UST Closure and Assessment Report to the Department; and submit a completed certificate of Financial Responsibility Form and evidence of financial assurance by April 16, 2022. The Department has assessed a total civil penalty in the amount of twenty-one thousand, eight hundred fifty dollars ($21,850.00). The Individual/Entity shall pay a civil penalty in the amount of twenty-one thousand, eight hundred fifty dollars **($21,850.00)** by April 16, 2022.

Update: The Individual/Entity did not file a Request for Review; therefore, the effective date of the Order is March 3, 2022. This has been referred to Office of General Counsel for further action.

2) Order Type and Number: Administrative Order 21-0501-UST
Order Date: February 22, 2022
Individual/Entity: **Estate of Albert Rollings, Sr.**
Facility: City Service
Location: 204 South Main Street
Jefferson, SC 29718
Mailing Address: P. O. Box 141
Jefferson, SC 29718-0141
County: Chesterfield
Previous Orders: AO 20-0202-UST ($17,250.00)
Permit/ID Number: 02300
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. Code Ann. § 44-2-60(A) (2018).

Summary: The Estate of Albert Rollings, Sr. (Individual/Entity) owns and operates underground storage tanks (USTs) in Chesterfield County, South Carolina. On May 4, 2021, the Department conducted a file review and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failure to pay annual UST registration fees.

Action: The Individual/Entity is required to submit annual UST registration fees and associated late fees for fiscal year 2022 in the amount of two hundred forty-two dollars ($242.00) by April 26, 2022. 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**) by April 26, 2022.

Update: The Individual/Entity did not file a Request for Review; therefore, the effective date of the Order is March 12, 2022.

3) Order Type and Number: Administrative Order 21-0544-UST
Order Date: March 1, 2022
Individual/Entity: **Russell T. Williford**
Facility: Morris Service Station
Location: 1502 Lockhart Highway
Union, SC 29379
Mailing Address: 107 Osborne Street
Union, SC 29379
County: Union
Previous Orders: None
Permit/ID Number: 15373
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, 280.34(c), 280.70(a), 280.242, and 280.242(b)(4) (2012 and Supp. 2020).

Summary: Russell T. Williford (Individual/Entity) owns and operates underground storage tanks (USTs) in Union County, South Carolina. On August 24, 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 provide records to the Department upon request; failed to continue release detection and/or corrosion protection for a temporarily closed UST; failed to have a Class A/B operator trained for the Facility; failed to physically visit and document quarterly site visits; and failed to pay annual tank registration fees (ATRFs).

Action: The Individual/Entity is required to: submit current passing corrosion protection system test results for the piping associated with the USTs at the Facility; submit proof a Class A/B operator has been trained and designated for the Facility; submit proof a Class A/B walkthrough/operator inspection log has been initiated and is being properly maintained; and paythe ATRFs and associated late fees for fiscal years 2020, 2021, and 2022 in the amount of one thousand, six hundred ninety-four dollars ($1,694.00) by May 3, 2022. The Department has assessed a total civil penalty in the amount of seven thousand, five hundred dollars ($7,500.00). The Individual/Entity shall pay a civil penalty in the amount of seven thousand, five hundred dollars **($7,500.00)** by May 3, 2022.

Update: The Individual/Entity did not file a Request for Review; therefore, the effective date of the Order is March 19, 2022.

4) Order Type and Number: Administrative Order 22-0049-UST
Order Date: March 10, 2022
Individual/Entity: **Pavan Parth, LLC**
Facility: Pavan Food Store 102
Location: 1048 South Main Street
Greenwood, SC 29646-3254
Mailing Address: 115 Lavender Hill Court
Simpsonville, SC 29681-5370
County: Greenwood
Previous Orders: AO 21-0225-UST ($6,300.00)
Permit/ID Number: 04734
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, 280.21(b), 280.31(a), and 280.70(c) (2012 and Supp. 2020).

Summary: Pavan Parth, LLC (Individual/Entity) owns and operates underground storage tanks (USTs) in Greenwood County, South Carolina. On December 9, 2021, the Department conducted a file review 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 protect an operating UST system from corrosion; failed to operate and maintain corrosion protection equipment continuously; and failed to properly abandon a temporarily closed UST system after twelve (12) months.

Action: The Individual/Entity is required to submit: a completed UST tank and Sludge Disposal form for the permanent closure of the USTs; within forty-five (45) days of the Department's approval of the Tank and Sludge Disposal form, permanently close the USTs; within sixty (60) days of permanent closure, an UST Closure and Assessment Report. The Department has assessed a total civil penalty in the amount of thirty-eight thousand, one hundred fifty dollars ($38,150.00). The Individual/Entity shall pay a civil penalty in the amount of thirty-eight thousand, one hundred fifty dollars **($38,150.00)**.

Update: The Individual/Entity did not file a Request for Review; therefore, the effective date of the Order is March 30, 2022.

5) Order Type and Number: Consent Order 22-0022-UST
Order Date: March 1, 2022
Individual/Entity: **Tammy White**
Facility: Value Mart 1
Location: 1461 Saint Delight Road
Sampit, SC 29440
Mailing Address: 1447 Indian Hut Road
Georgetown, SC 29440
County: Georgetown
Previous Orders: None
Permit/ID Number: 16263
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 61-92,280.21(a)(3), 280.31(b)(1), 280.70(c), 280.93, and 280.110(c), (2012 & Supp 2019).

Summary: Tammy White (Individual/Entity) owns underground storage tanks in Georgetown County, South Carolina. The Department conducted an inspection and issued a Notice of Alleged Violation on January 8, 2021. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to demonstrate financial responsibility for an UST system; failure to provide financial assurance to the Department upon request; failed to properly close a substandard UST system; failed to have a cathodic protection system tested at least once every three (3) years by a qualified tester; and failed to properly abandon a temporarily closed system after twelve (12) months.

Action: The Individual/Entity is required to: submit a completed Tank and Sludge Disposal Form, and, within sixty (60) days of the Department's approval of the Tank and Sludge Disposal Form, permanently close the USTs and submit an UST Closure and Assessment Report; submit a completed Certificate of Financial Responsibility Form and evidence of financial assurance by April 15, 2022**.** The Department has assessed a total civil penalty of eighteen thousand, nine hundred fifty dollars ($18,950.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand, two hundred dollars (**$2,200.00**) by April 15, 2022, and pay a suspended penalty in the amount of sixteen thousand, seven hundred fifty dollars ($16,750.00) should any requirement of the Order not be met.

Update: The Department received the Tank and Sludge Disposal Form March 28, 2022. On April 6, 2022, the Department received acceptable FR. The civil penalty was paid April 12, 2022.

6) Order Type and Number: Consent Order 21-0034-UST
Order Date: March 3, 2022
Individual/Entity: **South Carolina Department of Corrections**
Facility: Lieber Correctional Facility

Location: 136 Wilborn Avenue
Ridgeville, SC 29472
Mailing Address: P.O. Box 21787
Columbia, SC 29221
County: Dorchester
Previous Orders: None
Permit/ID Number: 10172
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, 280.40(a), 280.40(a)(1) (2012 & Supp 2020).

Summary: South Carolina Department of Corrections (Individual/Entity) owns and operates underground storage tanks in Dorchester County, South Carolina. The Department conducted an inspection and issued a Notice of Alleged Violation on December 22, 2020. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to provide adequate release detection method and failed to conduct monthly monitoring of an UST system.

Action: The Individual/Entity is required to: submit proof of an adequate release detection method and current release detection equipment operability test result and begin monthly monitoring by April 18, 2022. The Department has assessed a total civil penalty in the amount of three thousand, three hundred sixty-five dollars ($3,365.00). The Individual/Entity shall pay a **suspended penalty** in the amount of three thousand, three hundred sixty-five dollars (**$3,365.00**) should any requirements of the Order not be met.

Update: None.

7) Order Type and Number: Consent Order 21-0090-UST
Order Date: March 3, 2022
Individual/Entity: **South Carolina Department of Corrections**
Facility: Ridgeland Correctional Institute
Location: 5 Correctional Road
Ridgeland, SC 29936-4545
Mailing Address: P.O. Box 21787
Columbia, SC 29221
County: Jasper
Previous Orders: None
Permit/ID Number: 14967
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-60(A) et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 61-92, 280.35(a)(2), 280.40(a), 280.40(a)(3), and 280.41(b)(1), 280.41(b)(1)(i)(B) (2012 & Supp 2020).

Summary: South Carolina Department of Corrections (Individual/Entity) owns and operates underground storage tanks in Jasper County, South Carolina. The Department conducted an inspection and issued a Notice of Alleged Violation on January 12, 2021. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to inspect overfill prevention equipment at

least once every three (3) years; failed to provide adequate release detection method; failed to conduct tank release detection operability test annually; failed to perform piping release detection for piping installed on or before May 23, 2008; and failed to conduct annual tightness test or have monthly monitoring of pressurized piping.

Action: The Individual/Entity is required to: submit a current passing 0.2-gph release detection method for the 10,000-gallon diesel UST; submit evidence a line leak detector has been installed in the submersible turbine pump for the 10,000-gallon diesel UST followed by a function check; and submit overfill prevention device equipment test results for the 20,000-gallon regular UST and the 8,000-gallon diesel UST by April 18, 2022. The Department has assessed a total civil penalty in the amount of two thousand, three hundred ninety dollars ($2,390.00). The Individual/Entity shall pay a **suspended penalty** in the amount of two thousand, three hundred ninety dollars **($2,390.00)** should any requirements of the Order not be met.

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

8) Order Type and Number: Consent Order 21-0392-UST
Order Date: March 3, 2022
Individual/Entity: **South Carolina Department of Corrections**
Facility: Turbeville Correctional Institution
Location: 1578 Clarence Coker Highway
Turbeville, SC 29162-9419
Mailing Address: P.O. Box 21787
Columbia, SC 29221
County: Clarendon
Previous Orders: None
Permit/ID Number: 14857
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, 280.34(c), 280.35(a)(1), 280.35(a)(2), 280.40(a), 280.40(a)(3), 280.41(b)(1)(i)(B), 280.43(d), 280.44(a), 280.45(b)(1), and 280.50 (2012 & Supp 2020).

Summary: South Carolina Department of Corrections (Individual/Entity) owns and operates underground storage tanks in Clarendon County, South Carolina. The Department conducted an inspection and issued a Notice of Alleged Violation on June 8, 2021. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to provide records upon request; failed to prevent releases from spill buckets and/or containment sumps used for interstitial monitoring of piping; failed to inspect overfill prevention equipment at least once every three (3) years; failed to provide adequate release detection method; failed to conduct tank release detection operability test annually; failed to conduct annual tightness test or have monthly monitoring of pressurized piping; failed to conduct release detection using automatic tank gauge; failed to conduct automatic line leak detector and/or sump sensor test annually; failed to maintain records for at least one year; and failed to report a suspected release.

Action: The Individual/Entity is required to: submit a passing automatic tank gauge sensor/probe test results and current passing ATG for the 10,000-gallon off-road

diesel UST; passing line tightness, line leak detector, and function check test results for the 10,000-gallon off-road diesel UST; passing overfill equipment operability test results for all USTs; passing spill bucket integrity test results for the 10,000-gallon off-road diesel UST by April 18, 2022. The Department has assessed a total civil penalty in the amount of four thousand, five hundred ten dollars ($4,510.00). The Individual/Entity shall pay a **suspended penalty** in the amount of four thousand, five hundred ten dollars **($4,510.00)** should any requirement of the Order not be met.

Update: The Department has received all compliance documentation except a line leak detector function check and overfill operability test results for the 10,000-gallon off-road diesel UST.

9) Order Type and Number: Consent Order 22-0042-UST
Order Date: March 8, 2022
Individual/Entity: **S&M 786 Elko, LLC**
Facility: Elko Grocery
Location: 10193 Highway 78
Elko, SC 29826
Mailing Address: 2840 Brooklet-Leefield Road
Brooklet, GA 30415
County: Barnwell
Previous Orders: None
Permit/ID Number: 00882
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(b)(1), 280.34(c), 280.35(a)(1)(ii), 280.35(a)(2), 280.36(a)(1)(i), 280.40(a), 280.41(b)(1)(i)(B), 280.43(d), 280.43(g), 280.44(a), 280.45(b)(1), 280.93(a), 280.110(c), and 280.242(b)(3) (2012 & Supp 2020).

Summary: S&M 786 Elko, LLC (Individual/Entity) owns and operates underground storage tanks in Barnwell County, South Carolina. The Department conducted a file review and issued a Notice of Alleged Violation on November 18, 2021 and conducted an inspection and issued a Notice of Alleged Violation on December 7, 2021. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to have cathodic protection system tested at least once every three (3) years; failed to provide records to the Department upon request; failed to conduct triennial spill bucket integrity tests; failed to inspect overfill prevention equipment at least once every three (3) years; failed to conduct a monthly walkthrough inspection; failed to provide an adequate release detection method; failed to conduct annual tightness test or have monthly monitoring of pressurized piping; failed to conduct proper release detection using an automatic tank gauge; failed to conduct proper release detection using interstitial monitoring; failed to conduct an annual test of automatic line leak detectors and/or sump sensors; failed to maintain records for at least one (1) year; failed to demonstrate financial responsibility for an UST system; failed to submit evidence of financial assurance to the Department upon request; and failed to validate that monthly requirements have been performed.

Action: The Individual/Entity is required to: repair and/or replace the overfill prevention equipment and submit passing follow-up overfill operability test results for all USTs at the Facility; repair and/or replace sump sensors for all submersible turbine pump

sumps and submit passing follow-up sump sensor function check results for all STP sumps at the Facility; submit passing integrity test results for the spill buckets at the Facility; repair and/or replace the under dispenser containment sumps at the Facility; submit passing follow-up integrity test results for all under dispenser containment sumps at the Facility, and conduct a site check and submit the results to the Department for all under dispenser containment sumps at the Facility; repair and/or replace the STP sumps at the Facility; submit passing follow-up integrity test results for all STP sumps at the Facility, and conduct a site check and submit the results to the Department for all STP sumps at the Facility; repair and/or replace the cathodic protection system and submit passing follow-up cathodic protection system test results for all USTs at the Facility; submit proof that a Class A/B Operator/Walkthrough log (D-3185) is being maintained; submit proof that all Class A/B Operators have completed supplemental training; and submit a completed Certificate of Financial Responsibility form (D-3472) and evidence of financial assurance by April 22, 2022. The Department has assessed a total civil penalty in the amount of nine thousand, three hundred fifteen dollars ($9,315.00). The Individual/Entity shall pay a civil penalty in the amount of nine thousand, three hundred fifteen dollars **($9,315.00)** by April 22, 2022.

Update: The Department has received all of the compliance documentation except: proof the cathodic protection system has been repaired/replaced and passing follow-up cathodic protection system test results; proof that a Class A/B operator/Walkthrough log is being maintained; and a completed Certificate of Financial Responsibility and evidence of financial assurance. The civil penalty has not been paid.

10) Order Type and Number: Consent Order 21-0607-UST
Order Date: March 10, 2022
Individual/Entity: **McCall Farms, Inc.**
Facility: Hubs Grill & Grocery
Location: 116 Olanta Highway
Effingham, SC 29541
Mailing Address: 6615 South Irby Street
Florence, SC 29541-9711
County: Florence
Previous Orders: None
Permit/ID Number: 03453
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, 280.34(c), 280.70(a), 280.242, 280.242(b)(3) and 280.242(b)(4) (2012 and Supp. 2020).

Summary: McCall Farms, Inc. (Individual/Entity) owns and operates an underground storage tank (UST) in Florence County, South Carolina. On October 1, 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 provide records to the Department upon request; failed to continue release detection and/or corrosion protection for a temporarily closed UST; failed to have a Class A/B operator trained for the Facility; and failed to validate the monthly and quarterly requirements have been performed and documented.

Action: The Individual/Entity is required to: submit proof the UST contains less than one (1) inch of residue; submit proof a Class A/B operator has been trained and designated for the Facility; submit proof a Class A/B Operator/Walkthrough log been

initiated and is being properly maintained; and submit either proof a rectifier box has been installed and subsequent passing cathodic protection system test results or permanently close the UST by April 25, 2022. The Department has assessed a total civil penalty in the amount of two thousand, four hundred fifty dollars ($2,450.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand, four hundred fifty dollars **($2,450.00)** is due by April 25, 2022.

Update: None.

11) Order Type and Number: Consent Order 21-0472-UST
Order Date: March 31, 2022
Individual/Entity: **ARC ATMTPSC001, LLC**
Facility: Citibank Na, Inc.
Location: 11 Ewall Street
Mt. Pleasant, SC 29464
Mailing Address: 2325 East Cameblack Road
Phoenix, AZ 85016
County: Charleston
Previous Orders: None
Permit/ID Number: 18732
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)(1), 280.33(f), 280.35(a)(2), 280.40(a), 280.41(b)(1)(i)(B), 280.50, and 280.52 (2012 & Supp 2020).

Summary: ARC ATMTPSC001, LLC (Individual/Entity) owns and operates underground storage tanks in Charleston County, South Carolina. On July 17, 2021, the Department conducted a routine inspection and issued a Notice of Alleged Violation. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to ensure that release due to spilling or overfilling do not occur; failed to repair and/or replace a spill bucket which failed integrity testing; failed to inspect overfill prevention equipment at least once every three (3) years; failed to provide an adequate release detection method; failed to conduct annual tightness test or have monthly monitoring of pressurized piping; failed to report a suspected release; and failed to investigate a suspected release.

Action: The Individual/Entity is required to: conduct a site check at the diesel Tank #2 and submit results to the Department; submit proof the spill bucket for diesel Tank #2 has been repaired and/or replaced and submit passing follow-up hydrostatic test results to the Department; submit passing overfill prevention equipment operability test results for all USTs at the Facility; and install line leak detectors for the submersible turbine pumps for all USTs at the Facility and submit follow-up line leak detector function check results to the Department by May 31, 2022. The Department has assessed a total civil penalty of eight thousand, three hundred fifteen dollars ($8,315.00). The Individual/Entity shall pay a civil penalty of eight thousand, three hundred fifteen dollars **($8,315.00)** by May 16, 2022.

Update: None.

12) Order Type and Number: Consent Order 22-0078-UST

Order Date: March 31, 2022
Individual/Entity: **Ryder Truck Rentals, Inc.**
Facility: Ryder Truck Rentals, Inc. 0148A
Location: 615 Simuel Road
Spartanburg, SC 29301
Mailing Address: 16155 Park Road, Suite 140
Houston, TX 77084
County: Spartanburg
Previous Orders: None
Permit/ID Number: 08095
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: Ryder Truck Rentals, Inc. (Individual/Entity) operates an underground storage tank (UST) in Spartanburg County, South Carolina. On March 1, 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 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 16, 2022.

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

Solid Waste Enforcement

13) Order Type and Number: Administrative Order 21-12-SW
Order Date: March 3, 2022
Individual/Entity: **Joe Wilson**
Facility: Joe's Tires
Location: 101 East Smith Street
Timmonsville, SC 29161
Mailing Address: Same
County: Florence
Previous Orders: None
Permit/ID Number: None
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: Waste Tires, Regulation, 61-107.3 (2015).

Summary: Joe Wilson (Individual/Entity), operates a used tire facility located in Florence County, South Carolina. The Department conducted an inspection in response to a complaint and issued a Notice of Alleged Violation on October 26, 2021. The Individual/Entity has violated the South Carolina Solid Waste Policy and Management Act, the Solid Waste Management: Waste Tires Regulations as follows: failed to meet the exemption for requiring a permit by storing greater than one thousand (1,000) waste tires at the facility.

Action: The Individual/Entity is required to: remove and properly dispose of the waste tires in excess of one thousand (1,000); provide disposal receipts to the Department; and submit a waste tire hauler application form, if appropriate. The Department has assessed a total civil penalty of three thousand, five hundred dollars ($3,500.00). The Individual/Entity shall pay a civil penalty of three thousand, five hundred dollars **($3,500.00)** by May 3, 2022.

Update: The Individual/Entity did not file a Request for Review; therefore, the effective date of the Order is March 19, 2022.

14) Order Type and Number: Consent Order 21-16-SW
Order Date: March 1, 2022
Individual/Entity: **Town of Latta**
Facility: Town of Latta Composting Site
Location: 107 NW Railroad Avenue
Latta, SC 29565
Mailing Address: Same
County: Dillon
Previous Orders: None
Permit/ID Number: 171002-3001
Violations Cited: South Carolina Solid Waste Policy and Management Act of 1991 (Act), Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings, and Organic Residuals Regulation, R.61-107.4 (2014 & Supp. 2019), Part III E.13.b. and Permit 171002-3001, General Conditions, 5.

Summary: Town of Latta (Individual/Entity), is responsible for operating a Composting Facility in Dillon County, South Carolina. On September 7, 2021, the Department conducted a file review and determined that the Individual/Entity had not submitted its 2021 Annual Report. The Individual/Entity has violated the South Carolina Solid Waste Policy and Management Act, Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings, and Organic Residual Regulation, and the Permit as follows: failed to submit an annual report for fiscal year 2021.

Action: The Individual/Entity is required to: submit an annual report for fiscal year 2021; and pay a civil penalty in the amount of six hundred dollars **($600.00)** by April 15, 2022.

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

Hazardous Waste Enforcement

15) Order Type and Number: Consent Order 22-06-HW
Order Date: March 10, 2022
Individual/Entity: **Safety Kleen Systems, Inc.**
Facility: Safety Kleen Systems, Inc.
Location: 2818 Old Woodruff Road

Spartanburg, SC 29652
Mailing Address: Same
County: Spartanburg
Previous Orders: 19-7-HW ($13,500.00)
Permit/ID Number: SCD 981 031 040
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: Safety Kleen Systems, Inc. (Individual/Entity) specializes in the proper handling and disposal of both hazardous and non-hazardous waste at its facility located in Spartanburg County, South Carolina. The Department conducted an inspection at the facility on September 21, 2021. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act and the Hazardous Waste Management Regulations as follows: failed to record inspections in an inspection log; failed to remedy any deterioration or malfunction of equipment and record remedial action in an inspection log; stored transfer waste for greater than 10 days; exceeded storage limit capacity; failed to clean up spillage that occurred during processing; failed to measure shell, bottom, and top thickness of the hazardous waste tank; failed to maintain the secondary containment system; and failed to use appropriate spill and overflow controls.

Action: The Individual/Entity is required to: submit measurements for the top tank shell and bottom thickness and the visual inspections for the hazardous waste tank by April 11, 2022 and submit a Work Plan for the secondary containment system by May 11, 2022. The Department assessed a total civil penalty in the amount of thirty-five thousand dollars ($35,000.00). The Individual/Entity shall pay a civil penalty in the amount of thirty-five thousand dollars **($35,000.00)** by April 11, 2022.

Update: The civil penalty has been paid in full.

Infectious Waste Enforcement

16) Order Type and Number: Consent Order 22-05-IW
Order Date: March 7, 2022
Individual/Entity: **Roper Hospital**
Facility: Roper Hospital
Location: 316 Calhoun Street
Charleston, SC 29401
Mailing Address: Same
County: Charleston
Previous Orders: 20-04-IW ($16,680)
Permit/ID Number: SC10-0264G
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: Roper Hospital (Individual/Entity) is a non-profit, full-service hospital located in Charleston County, South Carolina. The Department conducted site visits on August 27, 2021, September 9, 2021, September 16, 2021, and October 5, 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 and manage infectious waste to prevent exposure to the public or release to the environment; offered infectious waste to a non-registered transporter; failed to package infectious waste in accordance with the requirements of R.61-105 Section I; failed to place and maintain all sharps in a rigid, leak-resistant, and puncture resistant containers; failed to maintain other types of infectious waste in rigid containers that were impervious to moisture; failed to use containers with sufficient strength to prevent bursting and tearing; failed to use plastic bags that were red or orange color with sufficient strength to prevent tearing; failed to use containers that were appropriate for storage, transportation, and treatment; 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; and failed to treat infectious waste prior to disposal.

Action: The Individual/Entity has corrected the violations. The Department has assessed a total civil penalty in the amount of fifty thousand dollars ($50,000.00). The Individual/Entity shall pay a civil penalty in the amount of fifty thousand dollars **($50,000.00)** by April 7, 2022.

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

17)

Order Type and Number:	Consent Order 22-06-IW
Order Date:	March 7, 2022
Individual/Entity:	**Bon Secours St. Francis Hospital**
Facility:	Bon Secours St. Francis Hospital
Location:	2095 Henry Tecklenburg Drive Charleston, SC 29414
Mailing Address:	Same
County:	Charleston
Previous Orders:	20-03-IW ($18,720.00) 20-04-IW ($16,680.00)
Permit/ID Number:	SC10-0263G
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: Bon Secours St. Francis Hospital (Individual/Entity) is a non-profit, full-service hospital located in Charleston County, South Carolina. The Department conducted site visits on September 28, 2021, and October 12, 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 and manage infectious waste to prevent exposure to the public or release to the environment; offered infectious waste to a non-registered transporter; failed to package infectious waste in accordance with the requirements of R.61-105 Section I; failed to place and maintain all sharps in a rigid, leak-resistant, and puncture resistant containers; failed to maintain other types of infectious waste in rigid containers that were impervious to moisture; failed to use containers with sufficient strength to prevent bursting and tearing; failed to use plastic bags that were red or orange color with sufficient strength to prevent tearing; failed to use containers that were appropriate for storage, transportation, and treatment; 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; and failed to treat infectious waste prior to disposal.

Action: The Individual/Entity has corrected the violations. The Department has assessed a total civil penalty in the amount of fifty-four thousand dollars ($54,000.00). The Individual/Entity shall pay a civil penalty in the amount of fifty-four thousand dollars **($54,000.00)** by April 7, 2022.

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

18) Order Type and Number: Consent Order 22-07-IW
Order Date: March 21, 2022
Individual/Entity: **Ralph H. Johnson VA Medical Center**
Facility: VA Medical Center
Location: 109 Bee Street
Charleston, SC 29401
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit/ID Number: SC10-0257G
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: Ralph H. Johnson VA Medical Center (Individual/Entity), operates a primary care facility in Charleston County, South Carolina. On September 20, 2021, the Department opened an investigation and conducted site visits on September 20, 2021, October 27, 2021, and November 2, 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 twenty-five thousand dollars ($25,000.00). The Individual/Entity shall pay a civil penalty of twenty-five thousand dollars **($25,000.00)** by April 21, 2022.

Update: None.

19) Order Type and Number: Consent Order 22-08-IW
Order Date: March 23, 2022
Individual/Entity: **Conway Medical Center**
Facility: Conway Medical Center
Location: 300 Singleton Ridge Road
Conway, SC 29526
Mailing Address: Same
County: Horry
Previous Orders: None
Permit/ID Number: SC26-0076G
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: Conway Medical Center (Individual/Entity), operates a non-profit full-service hospital located in Horry 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 use containers that had sufficient strength to prevent bursting and tearing; 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 April 22, 2022.

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

Mining Enforcement

20) Order Type and Number: Consent Order 22-01-MSWM
Order Date: March 1, 2021
Individual/Entity: **Kimberly Sheffield Lankford**
Facility: Sheffield Mine
Location: Fisher Road
Hampton County, SC
Mailing Address: 1462 Sidneys Road
Walterboro, SC 29488
County: Hampton
Previous Orders: None

Permit/ID Number: GP1-002342
Violations Cited: South Carolina Mining Act (2008 & Supp. 2015), the Mining Regulation, Section 20 (Supp. 2012) (Regulation), 340(B) and 210.

Summary: Kimberly Sheffield Lankford (Individual/Entity), owns and operates a mine in Hampton County, South Carolina. On November 4, 2021, the Department conducted an inspection in response to a complaint. The Individual/Entity has violated the South Carolina Mining Act and the Mining Regulation as follows: failed to obtain a permit from the Department prior to engaging in mining activities.

Action: The Individual/Entity has corrected the violations. 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 civil penalty in the amount of one thousand dollars ($1,000.00) was submitted to the Department on February 22, 2022. The Order is closed.

BUREAU OF WATER

Drinking Water Enforcement

21)
Order Type and Number: Consent Order 22-008-DW
Order Date: March 1, 2022
Individual/Entity: **City of Anderson**
Facility: Electric City Utilities
Location: Anderson, SC 29625
Mailing Address: 314 Tribble Street
Anderson, SC 29625
County: Anderson
Previous Orders: None
Permit/ID Number: 0410012
Violations Cited: S.C. Code Ann. Regs. 61-58.17.K(1)

Summary: The City of Anderson (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Anderson County, South Carolina. On January 11, 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 tested present for total coliform and E. coli, which resulted in a violation of the maximum contaminant level for E. coli.

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 March 31, 2022. The Department has assessed a total civil penalty in the amount of four thousand dollars ($4,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of four thousand dollars **($4,000.00)** should any requirement of the Order not be met.

Update: The Individual/Entity submitted a corrective action plan that was approved by the Department.

22) Order Type and Number: Consent Order 22-009-DW
Order Date: March 1, 2022
Individual/Entity: **Town of West Pelzer**
Facility: Town of West Pelzer
Location: 30 Main Street
West Pelzer, SC 29669
Mailing Address: Same
County: Anderson
Previous Orders: None
Permit/ID Number: 0410009
Violations Cited: S.C. Code Ann. Regs. 61-58.7

Summary: The Town of West Pelzer (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Anderson County, South Carolina. The Department conducted an inspection on December 17, 2021, and the PWS was rated unsatisfactory for failure to properly operate and maintain. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: the storage tank had not been inspected as required; there was a well that was no longer in service that had not been properly abandoned or converted to an irrigation well; fire flow records were not provided for Department review; and a procedures manual with monitoring records, programs, and inspection logs was not provided for Department review.

Action: The Individual/Entity is required to: convert the well that is no longer in service to an irrigation well and implement a standard operating procedure that ensures adequate staff are available to operate and maintain the PWS and manage the water programs by July 1, 2022; conduct an inspection of the vent screens, hatches, and other openings on the storage tank and submit to the Department a copy of the reports by July 1, 2022; complete an assessment to identify the location and condition of all of the PWS's valves and submit to the Department for review and approval a written valve maintenance program by December 1, 2022; flow test all of the fire hydrants located within the Town of West Pelzer's service area and submit the test reports to the Department for review and approval by December 1, 2022; and repair or replace any valves and hydrants documented as inadequate or inoperable within one hundred twenty days of the Department's approval of the reports. The Department has assessed a total civil penalty in the amount of four thousand dollars ($4,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of four thousand dollars **($4,000.00)** should any requirement of the Order not be met.

Update: None.

23) Order Type and Number: Consent Order 22-010-DW
Order Date: March 10, 2022
Individual/Entity: **Christine Fields & Robert C. Fields, Individually and d.b.a. Fields Purrysburg Road Water System**
Facility: Fields Purrysburg Road Water System
Location: 5977 Purrysburg Road

	Hardeeville, SC 29927
Mailing Address:	Same
County:	Jasper
Previous Orders:	None
Permit/ID Number:	2760019
Violations Cited:	S.C. Code Ann. Regs. 61-58.7 & 61-58.8.B

Summary: Christine Fields & Robert C. Fields, Individually and d.b.a. Fields Purrysburg Road Water System (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Jasper County, South Carolina. The Department conducted an inspection of the PWS on December 1, 2021, 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 well did not have a vent, concrete pad, sample tap, blow-off, or lockable well house; the sanitary seal was rusted and open at the juncture of the two haves; the storage tank was not secured with a fence that could be locked; the storage tank did not have a proper pressure gauge; a procedures manual with the associated programs and logs was not provided for Department review; an emergency preparedness plan was not provided for Department review; and the well serving the system was not permitted for public supply.

Action: The Individual/Entity is required to: submit a corrective action plan with a schedule of completion to resolve the unpermitted source of water by April 9, 2022; and within fifteen days of completion of the approved corrective action plan submit a written request for the intended use of the unpermitted well. 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 submitted a corrective action plan that was approved by the Department.

24)

Order Type and Number:	Consent Order 22-011-DW
Order Date:	March 21, 2022
Individual/Entity:	**City of Abbeville**
Facility:	City of Abbeville
Location:	406 Vienna Street Abbeville, SC 29620
Mailing Address:	P.O. Box 40 Abbeville, SC 29620
County:	Abbeville
Previous Orders:	None
Permit/ID Number:	0110001
Violations Cited:	S.C. Code Ann. Regs. 61-58.7.C(1); 61-58.7.E(1)

Summary: The City of Abbeville (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Abbeville County, South Carolina. On January 25, 2022, a Notice of Alleged Violation/Notice of Enforcement Conference was issued as a result of review of the December 2021 monthly operation report for the PWS. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: failed to provide a treatment operator of the

appropriate grade to be present and responsible for the surface water treatment plant when the plant was producing water for public consumption; and failed to provide a distribution operator of the appropriate grade.

Action: The Individual/Entity is required to: submit a standard operating procedure for providing operators of the appropriate grade as required by April 21, 2022. The Department has assessed a total civil penalty in the amount of six thousand, seven hundred eighty dollars ($6,780.00). The Individual/Entity shall pay a civil penalty in the amount of six thousand, seven hundred eighty dollars **($6,780.00)** by April 21, 2022.

Update: The civil penalty has been paid. The Individual/Entity submitted a standard operating procedure that was approved and implemented.

25)

Order Type and Number:	Consent Order 22-012-DW
Order Date:	March 21, 2022
Individual/Entity:	**Clarendon Hospital District**
Facility:	Pocatalico River Health and Rehab
Location:	326 South Mill Street Manning, SC 29201
Mailing Address:	P.O. Box 57 Manning, SC 29201
County:	Clarendon
Previous Orders:	None
Permit/ID Number:	34126-WS
Violations Cited:	S.C. Code Ann. Regs. 61-58.1.K(1)

Summary: Clarendon Hospital District (Individual/Entity) owns and is responsible for obtaining from the Department written approval to operate a drinking water distribution system located in Clarendon County, South Carolina. On February 11, 2022, a Notice of Alleged Violation/Notice of Enforcement Conference was issued as a result of review of Department records. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: failed to obtain written approval to operate from the Department prior to placing a drinking water distribution system into operation.

Action: The Individual/Entity has corrected the violations. 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 April 21, 2022.

Update: The civil penalty has been paid. On February 16, 2022, the Individual/Entity submitted the required documentation and the Department issued written approval to operate the drinking water distribution system.

26)

Order Type and Number:	Consent Order 22-013-DW
Order Date:	March 21, 2022
Individual/Entity:	**Janice Chaney, Individually and d.b.a. Colonial Drive**
Facility:	Colonial Drive
Location:	106 Colonial Drive West Columbia, SC 29172
Mailing Address:	442 Shumpert Road

	Gaston, SC 29053
County:	Lexington
Previous Orders:	None
Permit/ID Number:	3250106
Violations Cited:	S.C. Code Ann. Regs. 61-58.7

Summary: Janice Chaney, Individually and d.b.a. Colonial Drive (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 November 17, 2021, and the PWS was rated unsatisfactory for failure to properly operate and maintain. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: there were items stored around the well house that were potential sources of contamination; the wellhead was exposed to the elements; the inside of the well house was dirty; the insulation was in disrepair; the sanitary seal was rusted; the well did not have a concrete pad, screened air vent, sample tap, check valve, or blow-off; the well house was not locked; there was exposed electrical wiring; the outside of the storage tank was dirty; there were openings at the base of the well enclosure; and the well serving the system was not permitted for public supply.

Action: The Individual/Entity is required to submit a corrective action plan and schedule of implementation to resolve the unpermitted source of water by April 21, 2022; and within fifteen days of completion of the approved corrective action plan submit a written request for the intended use of the unpermitted well. The Department has assessed a total civil penalty in the amount of four thousand dollars ($4,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of four thousand dollars **($4,000.00)** should any requirement of the Order not be met.

Update: The Individual/Entity has contacted a professional well drilling company to help assess the options.

27)

Order Type and Number:	Consent Order 22-014-DW
Order Date:	March 24, 2022
Individual/Entity:	**Town of Lincolnville**
Facility:	Town of Lincolnville
Location:	141 West Broad Street Lincolnville, SC 29485
Mailing Address:	Same
County:	Charleston
Previous Orders:	None
Permit/ID Number:	1010007
Violations Cited:	S.C. Code Ann. Regs. 61-58. 17.H(2) & 61-58.13.C(3)(a)(i)

Summary: The Town of Lincolnville (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Charleston County, South Carolina. On January 26, 2022, and February 18, 2022, a violation was issued as a result of review of Department records. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: failure to conduct routine monthly monitoring for total coliforms, and failure to measure the residual disinfection level in the distribution system at the same point in the distribution system and at the same time as total coliforms are sampled.

Action: The Individual/Entity is required to: immediately implement routine monthly monitoring of the PWS for total coliforms and residual disinfection levels; and submit a standard operating procedure that will be followed to ensure that all monitoring and reporting requirements are complied with by April 23, 2022. The Department has assessed a total civil penalty in the amount of eight thousand three hundred sixty dollars ($8,360.00). The Individual/Entity shall pay a civil penalty in the amount of eight thousand three hundred sixty dollars (**$8,360.00**) by April 23, 2022.

Update: The Individual/Entity has implemented the required monitoring, and the civil penalty has been paid.

Water Pollution Enforcement

28) Order Type and Number: Consent Order 22-015-W
Order Date: March 1, 2022
Individual/Entity: **Horry Land Services, LLC**
Facility: Horry Land Services LLC/Mill Swamp Mine
Location: Little River, SC 29568
Mailing Address: 1390 Hwy 57 S
Little River, SC 29566
County: Horry
Previous Orders: None
Permit/ID Number: SCG731461
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 NPDES SCG0731461

Summary: Horry Land Services (Individual/Entity) owns and is responsible for the proper operation and maintenance of its mine dewatering facility (MDWF) in Horry County, South Carolina. On December 15, 2021, a Notice of Alleged Violation (NOAV) was issued as a result of a failure to monitor discharge and submit discharge monitoring reports to the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulations as follows: failed to monitor discharge and submit DMRs as specified in its National Pollutant Discharge Elimination System (NPDES) Permit.

Action: The Individual/Entity is required to: submit written notification by March 31, 2022, detailing how the Individual/Entity will ensure proper sampling and reporting in the future. The Department has assessed a total civil penalty in the amount of five thousand one hundred dollars ($5,100.00). The Individual/Entity shall pay a civil penalty in the amount of five thousand one hundred dollars **($5,100.00)** by March 31, 2022.

Update: None

29) Order Type and Number: Consent Order 22-016-W
Order Date: March 1, 2022
Individual/Entity: **Harbor Island Utilities, Inc.**
Facility: Harbor Island Utilities WWTF

Location: 2 Harbor Drive
Harbor Island, SC
Mailing Address: 31 Sora Rail Road
Kiawah Island, SC 29455
County: Beaufort
Previous Orders: None
Permit/ID Number: ND0088013
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d), Water Pollution Control Permits Regulation, S.C. Code Ann Regs. 61-9.122.41(a), and Part III. A of Permit ND0088013

Summary: Harbor Island Utilities, Inc. (Individual/Entity) owns and is responsible for a wastewater treatment facility (WWTF) located in Beaufort County, South Carolina. On November 18, 2021, a Notice of Alleged Violation (NOAV) was issued as a result of biochemical oxygen demand (BOD) violations reported on discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and the Water Pollution Control Permits Regulation, as follows: failed to comply with the permitted effluent limitations for BOD.

Action: The Individual/Entity is required to: submit written notification of the completion date of corrective actions to resolve the effluent violations by May 1, 2022; and demonstrate a six-monitoring event compliance confirmation period. The Department has assessed a total civil penalty in the amount of three thousand, five hundred dollars ($3,500.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand, five hundred dollars **($3,500.00)** by April 1, 2022.

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

30) Order Type and Number: Consent Order 22-017-W
Order Date: March 7, 2022
Individual/Entity: **City of Cayce**
Facility: Cayce WWTF
Location: Cayce, SC 29033
Mailing Address: 1800 12th Street Cayce, SC 29033
County: Lexington
Previous Orders: None
Permit/ID Number: SC0024147
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 NPDES SC0024147

Summary: The City of Cayce (Individual/Entity) owns and is responsible for the proper operation and maintenance of its wastewater treatment facility in Lexington County, South Carolina. On August 30, 2021, a Notice of Alleged Violation (NOAV) was issued as a result of Escherichia coli (E. coli) violations reported on discharge monitoring reports 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 limitations of NPDES Permit SC0024147 for E.coli.

Action: The Individual/Entity is required to: submit written notification of the completion date for all corrective actions necessary to resolve the violations by April 7, 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 three thousand five hundred dollars ($3,500.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand five hundred dollars **($3,500.00)** by April 7, 2022.

Update: The Individual/Entity has submitted payment of the assessed penalty and notification of the corrective action completion date.This Order has been closed.

31) Order Type and Number: Consent Order 22-018-W
Order Date: March 10, 2022
Individual/Entity: **Scenic Lake Park**
Facility: Scenic Lake Park WWTF
Location: Intersection of Hillside Drive and Ridgewood Drive, Rembert, SC 29128
Mailing Address: 4915 Ridgewood Drive, Rembert, SC 29128
County: Sumter
Previous Orders: None
Permit/ID Number: SC0031895
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d), Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.21(d), and National Pollutant Discharge Elimination System (NPDES) Permit SC0031895.

Summary: Scenic Lake Park (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) in Sumter County, South Carolina. On February 2, 2022, a Notice of Alleged Violation (NOAV) 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. The Department has assessed a total civil penalty in the amount of seven hundred dollars ($700.00). The Individual/Entity shall pay in two installments a civil penalty in the amount of seven hundred dollars **($700.00)** by April 9, 2022 and June 8, 2022.

Update: The Individual/Entity has paid one installment in the amount of three hundred fifty dollars ($350.00) as of March 10, 2022.

32) Order Type and Number: Consent Order 22-019-W
Order Date: March 21, 2022
Individual/Entity: **Federal Pacific Electric Company**
Facility: Federal Pacific Electric Co. Odell Dam
Location: Edgefield, SC 29824
Mailing Address: 450 Montbrook Lane Knoxville, TN 37919
County: Edgefield

Previous Orders: None
Permit/ID Number: SC0047813
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 NPDES SC0024147

Summary: Federal Pacific Electric Company (Individual/Entity) owns and is responsible for the proper operation and maintenance of its groundwater treatment system in Edgefield County, South Carolina. On September 21, 2021, a Notice of Alleged Violation (NOAV) was issued as a result of Trichloroethene (TCE) violations reported on discharge monitoring reports 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 limitations of NPDES Permit SC0047813 for TCE.

Action: The Individual/Entity is required to: submit written notification of the completion date for all corrective actions necessary to resolve the violations by April 21, 2022; conduct a six (6) monitoring event compliance confirmation period upon completion of corrective actions; and implement engineered upgrades to the GTS should additional violations be observed during the compliance confirmation period. The Department has assessed a total civil penalty in the amount of four thousand dollars ($4,000.00)**.** The Individual/Entity shall pay a civil penalty in the amount of four thousand dollars **($4,000.00)** by April 21, 2022.

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

33) Order Type and Number: Consent Order 22-020-W
Order Date: March 21, 2022
Individual/Entity: **Town of Williston**
Facility: Rosemary Creek WWTF
Location: 706 Lake Drive
Williston, SC 29853
Mailing Address: P.O. Box 414
Williston, SC 29853
County: Barnwell
Previous Orders: None
Permit/ID Number: ND0063061
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d), Water Pollution Control Permits Regulation, S.C. Code Ann Regs. 61-9.122.41(e), and Part II.E. of Permit ND0063061

Summary: Town of Williston (Individual/Entity) owns and is responsible for the Rosemary Creek WWTF located in Barnwell County, South Carolina. On January 6, 2022, a Notice of Alleged Violation (NOAV) was issued as a result of unsatisfactory ratings during compliance evaluation inspections (CEIs) conducted by the Department in June 2021 and August 2021. The Individual/Entity has violated the Pollution Control Act and the Water Pollution Control Permits Regulation, as follows: failed to properly operate and maintain in good working order and operate as efficiently as possible all facilities and systems of treatment and control.

Action: The Individual/Entity is required to: submit notarized documentation that it has finalized a plan for securing funding for necessary improvements of the WWTF by April 21, 2022; submit a preliminary engineering report (PER) detailing necessary corrective actions and upgrades by May 21, 2022; submit proper documents for a Permit to Construct for necessary upgrades within ninety (90) days following Department approval of the PER; and complete all construction activities associated with the WWTF to attain compliance within one hundred eighty (180) days following issuance of a construction permit. 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)** by April 21, 2022.

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

34) Order Type and Number: Consent Order 22-021-W
Order Date: March 28, 2022
Individual/Entity: **Town of New Ellenton**
Facility: Town of New Ellenton WWTF
Location: 5344 White Pond Road
New Ellenton, SC 29809
Mailing Address: P.O. Box 459
New Ellenton, SC 29809
County: Aiken
Previous Orders: None
Permit/ID Number: SC0068454
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1- 110 (d) (2008 & Supp. 2021); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a) (2011).

Summary: The Town of New Ellenton (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Aiken County, South Carolina. On August 18, 2021, a Notice of Unsatisfactory Inspection was issued as a result of an unsatisfactory Compliance Sampling Inspection (CSI) conducted by the Department. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulation as follows: failed to maintain and operated the WWTF in accordance with State Land Application Discharge Permit ND0068454.

Action: The Individual/Entity is required to: submit a notarized document certifying all sprinkler heads at the designated spray field are operational by April 27, 2022; submit an Odor Abatement Plan that meets the requirements of the Permit by June 27, 2022; and submit a notarized document certifying that the liner in lagoon #2 of the WWTF has been replaced and is operating in accordance with Permit by December 31, 2023. 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 April 27, 2022.

Update: No updates to report.

BUREAU OF AIR QUALITY

35) Order Type and Number: Administrative Order 22-003-A
Order Date: March 1, 2022
Individual/Entity: **Mr. Rodney Brooks, Individually And d.b.a. Brooks Tree Service**
Facility: N/A
Location: 5420 Highway 9
Inman, SC 29349
Mailing Address: Same
County: Spartanburg
Previous Orders: None
Permit/ID Number: N/A
Violations Cited: South Carolina Code Ann. Regs. 61-62.2, *Prohibition of Open Burning*

Summary: Mr. Rodney Brooks, Individually and d.b.a. Brooks Tree Service (Individual/Entity), is a resident of the property located in Spartanburg County, South Carolina. The Department conducted an open burning investigation on May 4, 2019, and April 29, 2021. The Individual/Entity violated South Carolina Air Pollution Control Regulations, as follows: burned materials other than those allowed by Section I of the regulations, specifically land clearing debris that did not originate on site and wooden power poles.

Action: The Individual/Entity is required to cease all open burning except in accordance with the open burning regulations. The Department has assessed a total civil penalty in the amount of six thousand dollars ($6,000.00). The Individual/Entity shall pay a penalty in the amount of six thousand dollars (**$6,000.00**) by March 31, 2022.

Update: None

36) Order Type and Number: Administrative Order 22-004-A
Order Date: March 1, 2022
Individual/Entity: **Wayne Ledbetter**
Facility: N/A
Location: 963 Tubbs Mountain Road
Ladson, SC 29456
Mailing Address: Same
County: Greenville
Previous Orders: None
Permit/ID Number: N/A
Violations Cited: South Carolina Code Ann. Regs. 61-62.2, *Prohibition of Open Burning*

Summary: Wayne Ledbetter (Individual/Entity), is a resident of the property located in Greenville County, South Carolina. The Department conducted an open burning investigation on June 3, 2020, March 8, 2021, and April 7, 2021. The Individual/Entity violated South Carolina Air Pollution Control Regulations, as follows: burned materials other than those allowed by Section I of the regulation, specifically land clearing debris that did not originate onsite.

Action: The Individual/Entity is required to: cease all open burning except in accordance with the open burning regulations. The Department has assessed a total civil penalty in the amount of six thousand dollars ($6,000.00). The Individual/Entity shall pay a penalty in the amount of six thousand dollars (**$6,000.00**) by March 31, 2022.

Update: None

37) Order Type and Number: Administrative Order 22-007-A
Order Date: March 21, 2022
Individual/Entity: **Specialty Vermiculite, LLC**
Facility: Specialty Vermiculite, LLC
Location: 26383 Highway 221 North
Enoree, SC, 29335-6609
Mailing Address: Same
County: Laurens
Previous Orders: None
Permit/ID Number: 1520-0015
Violations Cited: S.C. Code Ann. Regs. 61-62.1, Section II, *Permit Requirements*

Summary: Specialty Vermiculite, LLC (Individual/Entity), operates a vermiculite plant that recovers raw ore through mining and cleaning processes at its facility located in Laurens County, South Carolina. On January 15, 2020, the Department conducted an inspection. The Individual/Entity has violated South Carolina Air Pollution Control Regulations, as follows: failed to maintain documentation demonstrating the calibration dates for gauges associated with baghouses; failed to maintain records of baghouse pressure drop readings; failed to provide maintenance records for the baghouse cleaning systems, dust collection hoppers, and conveying systems from September 2018 to June 18, 2020; failed to ensure that all baghouses were in place and operational whenever processes controlled by it were operating; failed to maintain weekly operation and maintenance (O&M) records for the cyclones; failed to maintain documentation of weekly O&M checks and daily pressure drop for the scrubbers; failed to maintain records of daily dust inspections for the bin vent filters; failed to maintain documentation of monthly and 12-month rolling sums for particulate matter (PM), PM_{10} and $PM_{2.5}$; failed to submit semiannual reports for operating range exceedances; and failed to submit an annual report of calculated values and twelve-month rolling sums for PM, PM_{10}, and $PM_{2.5}$ emissions.

Action: The Individual/Entity is required to: comply with all terms and conditions of State Operating Permit 1520-0015 and to submit to the Department monthly and 12-month rolling sums for PM, PM_{10} and $PM_{2.5}$, for the period of January 2020 to August 2021. The Department has assessed a total civil penalty in the amount of nine thousand dollars ($9,000.00). The Individual/Entity shall pay a penalty in the amount of nine thousand dollars **($9,000.00)** by April 21, 2022**.**

Update: None

38) Order Type and Number: Consent Order 22-005-A
Order Date: March 8, 2022
Individual/Entity: **Georgia Pacific Wood Products LLC**
Facility: Prosperity Plywood Plant
Location: 600 Georgia Pacific Blvd.

Prosperity, SC 29127
Mailing Address: Same
County: Newberry
Previous Orders: None
Permit/ID Number: 1780-0008
Violations Cited: U.S. EPA Regulations at 40 CFR Part 60 and S.C. Code Ann. Regs 61-62.60 (Supp. 2022), *Standards of Performance for New Stationary Sources*, Subpart Db, *Standards of Performance for Industrial-Commercial-Institutional Steam Generating Units*

Summary: Georgia Pacific (Individual/Entity), produces plywood from southern yellow pine logs at its facility located in Newberry County, South Carolina. The Individual/Entity conducted a Department-approved source test for particulate matter on April 27, 2021. The Individual/Entity has violated U.S. EPA and South Carolina Air Pollution Control Regulations, as follows: exceeded its particulate matter emission limit on the Boiler during a Department-approved source test.

Action: The Individual/Entity is required to: limit PM emissions on the Boiler to 0.10 lb/MMBtu. 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 April 8, 2022.

Update: The civil penalty has been paid.

39) Order Type and Number: Consent Order 22-006-A
Order Date: March 21, 2022
Individual/Entity: **Vanessa Unabia**
Facility: Same
Location: 1356 East Georgia Road
Woodruff, SC 29388
Mailing Address: Same
County: Spartanburg
Previous Orders: None
Permit/ID Number: N/A
Violations Cited: S.C. Code Ann. Regs. 61-62.2 (2011 & Supp. 2021), *Prohibition of Open Burning*.

Summary: Vanessa Unabia (Individual/Entity), is a resident of property located in Spartanburg County, South Carolina. The Department conducted an open burning investigation on December 11, 2017, April 1, 2019, and April 28, 2020. The Individual/Entity has violated South Carolina Air Pollution Control Regulations, as follows: burned materials other than those allowed by Section I of the regulation, specifically household garbage.

Action: The Individual/Entity is required to: cease all open burning except as in accordance with the open burning regulations. The Department has assessed a total civil penalty in the amount of five hundred dollars ($500.00). The Individual/Entity shall pay a penalty in the amount of five hundred dollars (**$500.00**) by April 21, 2022.

Update: None

40) Order Type and Number: Consent Order 22-008-A
Order Date: March 31, 2022
Individual/Entity: **Plasman SC Inc.**
Facility: Same
Location: 1000 Robinson Road
Greer, SC 29651-6721
Mailing Address: Same
County: Spartanburg
Previous Orders: 21-009-A ($7,500.00)
Permit/ID Number: 2060-0540
Violations Cited: S.C. Code Ann. Regs. 61-62.1, Section II, *Permit Requirements*

Summary: Plasman SC Inc. (Individual/Entity), is a manufacturer of plastic automotive exterior parts located in Spartanburg County, South Carolina. On September 10, 2021, the Department conducted an inspection. The Individual/Entity has violated South Carolina Air Pollution Control Regulations, as follows: failed to document daily pressure drop readings on each scrubber during each shift of source operation; failed to document liquid flow readings on each scrubber during each shift of source operation; and failed to record temperature readings every 15 minutes while RTO-1 was in operation.

Action: The Individual/Entity is required to comply with all terms and conditions of State Operating Permit 2060-0540. The Department has assessed a total civil penalty in the amount of seven thousand five hundred dollars ($7,500.00). The Individual/Entity shall pay a penalty in the amount of seven thousand five hundred dollars **($7,500.00)** by April 31, 2022.

Update: None

BUREAU OF ENVIRONMENTAL HEALTH SERVICES

Food Safety Enforcement

41) Order Type and Number: Consent Order 22-08-FOOD
Order Date: March 2, 2022
Individual/Entity: **Fatz**
Facility: Fatz
Location: 179 East Corporate Center Drive
Clinton, SC 29325
Mailing Address: 1361 West Wade Hampton Boulevard
Suite F, Box 6
Greer, SC 29650
County: Laurens
Previous Orders: 21-19-FOOD ($800.00)
Permit Number: 30-206-01552
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Fatz (Individual/Entity) operates a restaurant located in Laurens County, South Carolina. The Department conducted an inspection on January 6, 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 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 dollars ($1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars (**$1,000.00**) on or before April 2, 2022.

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

42)

Order Type and Number:	Consent Order 22-02-FOOD
Order Date:	March 3, 2022
Individual/Entity:	**Jean May Hong d.b.a. Asian Bistro**
Facility:	Asian Bistro
Location:	906-3 Tiger Boulevard Clemson, SC 29631
Mailing Address:	1237 Highway 182 Fair Play, SC 29643
County:	Pickens
Previous Orders:	None
Permit Number:	39-206-02213
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Jean May Hong, d.b.a. Asian Bistro, (Individual/Entity) operates a restaurant located in Pickens County, South Carolina. The Department conducted inspections on December 20, 2021, December 29, 2021, and January 7, 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.

43)

Order Type and Number:	Consent Order 22-07-FOOD
Order Date:	March 8, 2022
Individual/Entity:	**Sam's Club #6203 Bakery**
Facility:	Sam's Club #6203 Bakery
Location:	350 Harbison Boulevard Columbia, SC 29212
Mailing Address:	702 S.W. 8th Street Bentonville, AR 72716
County:	Lexington

Previous Orders: None
Permit Number: 32-206-02533
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Sam's Club #6203 Bakery (Individual/Entity) operates a bakery located in Lexington County, South Carolina. The Department conducted inspections on December 30, 2021, January 7, 2022, and January 14, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that the temperature of the fresh hot water sanitizing rinse as it enters the manifold, may not be more than 194 degrees in a mechanical operation, or less than 165 degrees for a stationary rack, single temperature machine; or less than 180 degrees for all other machines.

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.

44) Order Type and Number: Consent Order 21-29-FOOD
Order Date: March 10, 2022
Individual/Entity: **Cajun Operating Company d.b.a. Church's Chicken #823**
Facility: Church's Chicken #823
Location: 2001 Broad River Road
Columbia, SC 29210
Mailing Address: 980 Hammond Drive, Suite 1100
Atlanta, GA 30328
County: Richland
Previous Orders: 2019-206-03-030 ($200.00);
2021-03-FOOD ($500.00)
Permit Number: 40-206-08254
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Cajun Operating Company d.b.a. Church's Chicken #823 (Individual/Entity) operates a restaurant located in Richland County, South Carolina. The Department conducted inspections on July 23, 2021, August 2, 2021, August 12, 2021, November 5, 2021, November 15, 2021, November 23, 2021, December 3, 2021, and December 13, 2021. 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; failed to ensure that equipment is maintained in a state of repair and condition that meets the regulation requirements; failed to keep food contact surfaces of cooking equipment and pans free of encrusted grease deposits and other soil accumulations and non-food contact surfaces clean and free of accumulation of dust, dirt, food residue, and other debris; failed to ensure that physical facilities were maintained in good repair; and failed to clean the physical facilities as often as necessary to keep them clean.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of two thousand, five

hundred dollars ($2,500.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand, five hundred dollars (**$2,500.00**).

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

45) Order Type and Number: Consent Order 21-36-FOOD
Order Date: March 10, 2022
Individual/Entity: **Bruce Gerald d.b.a. Bruce's Grill & Convenience**
Facility: Bruce's Grill & Convenience
Location: 6475 Highway 701 North, Conway, SC 29526
Mailing Address: Same
County: Horry
Previous Orders: N/A
Permit Number: 26-206-02220
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Bruce Gerald d.b.a Bruce's Grill & Convenience (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on November 8, 2021, November 17, 2021, November 23, 2021, and November 29, 2021. 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, 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 provide a test kit or other device that accurately measures the concentration of MG/L of sanitizing solutions, and failed to ensure that a handwashing sink was located to allow convenient use by employees, in food preparation, food dispensing, and warewashing areas; and in, or immediately adjacent to, toilet rooms.

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 hundred dollars ($2,000.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand hundred dollars **($2,000.00) on or before April 10, 2022**.

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

46) Order Type and Number: Consent Order 22-11-FOOD
Order Date: March 10, 2022
Individual/Entity: **Nickolas Carpio d.b.a. Jade Hibachi**
Facility: Jade Hibachi
Location: 201 Graduate Road, Unit 107, Conway, SC 29526
Mailing Address: 104 Jessica Lakes Drive, Conway, SC 29526
County: Horry
Previous Orders: 2016-206-06-131 ($1,200.00);

2018-206-06-125 ($2,000.00);
2019-206-06-044 ($1,250.00);
2019-206-06-080 ($1,250.00);
2019-206-06-091 ($3,000.00)

Permit Number: 26-206-10472
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Nickolas Carpio d.b.a Jade Hibachi (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted inspections on June 4, 2021, January 5, 2022, January 13, 2022, and January 24, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that refrigerated, ready-to-eat, time/temperature control for safety foods were discarded if the temperature and time combination exceeded seven (7) days or if the package was not properly date marked; failed to ensure that during pauses in food preparation or dispensing, food preparation and dispensing utensils were stored in the food with their handles above the top of the food; failed to clean non-food contact surfaces at a frequency to preclude accumulation of soil residues; failed to ensure that nonfood-contact surfaces are free of unnecessary ledges, projections, and crevices, and designed and constructed to allow easy cleaning and to facilitate maintenance; and failed to clean the physical facilities as often as necessary to keep them clean.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. The Department has assessed a total civil penalty in the amount of one thousand, seven hundred fifty dollars ($1,750.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, seven hundred fifty dollars **($1,750.00)** by April 10, 2022.

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

47) Order Type and Number: Consent Order 22-16-FOOD
Order Date: March 18, 2022
Individual/Entity: **Kiss Café**
Facility: Kiss Café
Location: 1802 Crowne Commons Way
Johns Island, SC 29455
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit Number: 10-206-12077
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Kiss Café (Individual/Entity) operates a restaurant located in Charleston County, South Carolina. The Department conducted inspections on January 21, 2022, January 28, 2022, and February 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 foods 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 five hundred fifty

dollars ($550.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred fifty dollars **($550.00)** by April 18, 2022.

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

48) Order Type and Number: Consent Order 22-19-FOOD
Order Date: March 18, 2022
Individual/Entity: **Saigon Café Restaurant**
Facility: Saigon Café Restaurant
Location: 1943 A Mr. Joe White Avenue
Myrtle Beach, SC 29577
Mailing Address: Same
County: Horry
Previous Orders: None
Permit Number: 26-206-13706
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Saigon Café Restaurant (Individual/Entity) operates a restaurant located in Horry County, South Carolina. The Department conducted an inspection on February 18, 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)** by April 18, 2022.

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

49) Order Type and Number: Consent Order 22-13-FOOD
Order Date: March 24, 2022
Individual/Entity: **Asian Buffet**
Facility: Asian Buffet
Location: 364 Market Street
Seneca, SC 29678
Mailing Address: Same
County: Oconee
Previous Orders: None
Permit Number: 37-206-01280
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Asian Buffet (Individual/Entity) operates a restaurant located in Oconee County, South Carolina. The Department conducted inspections on January 13, 2022, January 20, 2022, and January 28, 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.

50) Order Type and Number: Consent Order 22-15-FOOD
Order Date: March 24, 2022
Individual/Entity: **Circle K #2705133**
Facility: Circle K #2705133
Location: 2600 Sunset Boulevard
West Columbia, SC 29169
Mailing Address: 2550 West Tyvola Road
Charlotte, NC 28217
County: Lexington
Previous Orders: None
Permit Number: 32-206-07175
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Circle K #2705133 (Individual/Entity) operates a convenience store located in Lexington County, South Carolina. The Department conducted inspections on January 11, 2022, January 24, 2022, and February 11, 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.

51) Order Type and Number: Consent Order 22-13-FOOD
Order Date: March 31, 2022
Individual/Entity: **Twin Peaks Columbia**
Facility: Twin Peaks Columbia
Location: 600 Gervais Street
Columbia, SC 29201
Mailing Address: 3365 Piedmont Road, NE, Suite 1050
Atlanta, GA 30305
County: Richland
Previous Orders: None
Permit Number: 40-206-07536
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Twin Peaks Columbia (Individual/Entity) operates a restaurant located in Richland County, South Carolina. The Department conducted inspections on January 4, 2022, January 13, 2022, and January 20, 2022. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure written procedures were in place and made available to the Department when the facility uses time as a public health control.

Action: The Individual/Entity is required to operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25. 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.

On-Site Wastewater Enforcement

52)

Order Type and Number:	Administrative Order 22-007-OSWW
Order Date:	March 3, 2022
Individual/Entity:	**Salomon Colin**
Facility:	Salomon Colin
Location:	751 Lacey Lane Seneca, SC 29672
Mailing Address:	Same
County:	Oconee
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Salomon Colin (Individual/Entity) owns property located in Oconee County, South Carolina. The Department conducted an investigation on September 23, 2021 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: On April 22, 2022, the Department has made a final attempt to contact the Individual/Entity by an e-mail address since USPS records are not reflecting the current status of the Demand Letter. If the Department is unable to obtain corrective action on or before April 27, 2022, a referral will be made to OGC for a complaint to be filed in the Administrative Law Court.

53) Order Type and Number: Administrative Order 22-008-OSWW
Order Date: March 3, 2022
Individual/Entity: **Christopher Turner**
Facility: Christopher Turner
Location: 346 Stewart Gin Road
Liberty, SC 29657
Mailing Address: Same
County: Pickens
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Christopher Turner (Individual/Entity) owns property located in Pickens County, South Carolina. The Department conducted an investigation on January 26, 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 personnel have confirmed with the licensed OSWW contractor that repairs will be completed on or before May 1, 2022.

54) Order Type and Number: Consent Order 22-011-OSWW
Order Date: March 23, 2022
Individual/Entity: **Don Foster, d.b.a. Don Foster's Construction and Asphalt Paving Co., Inc.**
Facility: Don Foster, d.b.a. Don Foster's Construction and Asphalt Paving Co., Inc.
Location: 377 Vernon Foster Road
Union, SC 29379
Mailing Address: Same
County: Union
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Don Foster, d.b.a. Don Foster's Construction and Asphalt Paving Co., Inc. (Individual/Entity) installed OSWW systems at two properties located in Union County, South Carolina. The Department conducted review of documents on November 22, 2021 and determined that the drainlines for both installations had an elevation

differential of greater than two inches throughout the trench and that the second installation was installed using an alternate product that was not allowed per 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, repaired, and cleaned in accordance with S.C. Regulation 61-56 and permits issued by the Department; and failed to ensure the elevation differential in the drainfield trenches was not greater than two inches.

Action: The Individual/Entity is required to cease and desist installing OSWW systems outside the requirements of the permit and cease and desist installing OSWW systems where the elevation differential in the drainfield trenches is greater than two inches. 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 and paid the civil penalty. 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

May 5, 2022

(X) ACTION/DECISION
( ) INFORMATION

I. **TITLE**: Request for Placement of Daridorexant in Schedule IV for Controlled Substances in South Carolina

II. **SUBJECT:** Placement of Daridorexant in Schedule IV for Controlled Substances

III. **FACTS:**

Controlled substances are governed by the South Carolina Controlled Substances Act ("CSA"), Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule IV substances are listed in Section 44-53-250 of the South Carolina Code of Laws. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances 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 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 January 7, 2022, the United States Food and Drug Administration ("FDA") approved a new drug application for QUIVIVIQ (daridorexant) tablets for the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance. The Department of Health and Human Services ("HHS") provided the Drug Enforcement Administration ("DEA") with a scheduling recommendation to place daridorexant and its salts in schedule IV of the Controlled Substances Act ("CSA"). In accordance with the CSA, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, DEA issued an interim final rule placing daridorexant in schedule IV, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of such isomers

is possible within the specific chemical designation, thereby facilitating the commercial distribution of QUIVIVIQ as a lawful controlled substance. This interim final became effective April 7, 2022, *Federal Register*, Volume 87, Number 67, pages 20313-20318; *https:// www.govinfo.gov/content/pkg/FR-2022-04-07/pdf/2022-07322.pdf*.

IV. ANALYSIS:

Daridorexant, chemically known as [(S)-2-(5-chloro-4-methyl-1Hbenzo[d]imidazol-2-yl)-2-methylpyrrolidin-1-yl](5-methoxy-2-(2H-1,2,3-triazol-2-yl)phenyl)methanone, is a new molecular entity ("NME") with Central Nervous System ("CNS") activity. Daridorexant is a dual orexin receptor antagonist that inhibits the orexin neuropeptide-induced activation of the orexin receptor type 1 ("OX1R") and orexin receptor type 2 ("OX2R") subtypes. Daridorexant shares chemical structure and pharmacological mechanism of action with certain schedule IV CNS depressants such as suvorexant and lemborexant. On January 8, 2021, Idorsia Pharmaceuticals, Ltd ("Sponsor") submitted a New Drug Application ("NDA") to FDA for QUIVIVIQ (daridorexant) tablets for use as a treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. On January 7, 2022, DEA received notification that FDA, on the same date, approved this NDA. The recommended dosage is 25–50 mg once per night, taken orally within 30 minutes before going to bed, with at least seven hours remaining prior to planned awakening.

On December 22, 2021, DEA received from HHS a scientific and medical evaluation entitled ''Basis for the Recommendation to Control Daridorexant and its Salts in schedule IV 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 daridorexant, along with HHS's recommendation to control daridorexant and its salts under schedule IV 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 daridorexant meets the 21 U.S.C. 812(b)(4) criteria for placement in schedule IV 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 daridorexant as a schedule IV 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) Daridorexant has a low potential for abuse relative to the drugs or other substances in Schedule III.

2) Daridorexant has a currently accepted medical use in treatment in the United States.

3) Abuse of daridorexant may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

V. RECOMMENDATION:

Pursuant to S.C. Code Section 44-53-160(C), the Department recommends placing daridorexant in schedule IV including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts

of such isomers is possible within the specific chemical designation and the amendment of Section 44-53-250 of the South Carolina Controlled Substances Act to include:

( ) Daridorexant [(S)-2-(5-chloro-4-methyl-1Hbenzo[d]imidazol-2-yl)-2-methylpyrrolidin-1-yl](5-methoxy-2- (2H-1,2,3-triazol-2- yl)phenyl) methanone

Submitted by:

Lisa Thomson
Director, Bureau of Drug Control

Gwen Thompson
Director for Healthcare Quality

Attachment:
Federal Register, Volume 87, Number 67, April 7, 2022

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–949]

Schedules of Controlled Substances: Placement of Daridorexant in Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule with request for comments.

SUMMARY: On January 7, 2022, the United States Food and Drug Administration approved a new drug application for QUIVIVIQ (daridorexant) tablets for the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance. The Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place daridorexant and its salts in schedule IV 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 daridorexant in schedule IV, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of such isomers is possible within the specific chemical designation, thereby facilitating the commercial distribution of QUIVIVIQ as a lawful controlled substance.

DATES: The effective date of this rule is April 7, 2022. Comments must be submitted electronically or postmarked on or before May 9, 2022. 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.

Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before May 9, 2022.

ADDRESSES: 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). To ensure proper handling of comments, please reference ''Docket No. DEA–949'' 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 Morrissette Drive, Springfield, VA 22152.
- *Hearing requests:* All requests for 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 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette 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

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

[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.

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).

Daridorexant, chemically known as [(S)-2-(5-chloro-4-methyl-1*H*-benzo[*d*]imidazol-2-yl)-2-methylpyrrolidin-1-yl](5-methoxy-2-(2*H*-1,2,3-triazol-2-yl)phenyl)methanone, is a new molecular entity (NME) with CNS activity. Daridorexant is a dual orexin receptor antagonist that inhibits the orexin neuropeptide-induced activation of the orexin receptor type 1 (OX1R) and orexin receptor type 2 (OX2R) subtypes. Daridorexant shares chemical structure and pharmacological mechanism of action with certain schedule IV CNS depressants such as suvorexant and lemborexant.

On January 8, 2021, Idorsia Pharmaceuticals, Ltd (Sponsor) submitted an NDA to FDA for QUIVIVIQ (daridorexant) tablets for use as a treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. On January 7, 2022, DEA received notification that FDA, on the same date, approved this NDA. The recommended dosage is 25–50 mg once per night, taken orally within 30 minutes before going to bed, with at least seven hours remaining prior to planned awakening.

Determination To Schedule Daridorexant

On December 22, 2021, DEA received from HHS a scientific and medical evaluation entitled ''Basis for the Recommendation to Control Daridorexant and its Salts in schedule IV 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 daridorexant, along with HHS's recommendation to control daridorexant and its salts under schedule IV 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 daridorexant meets the 21 U.S.C. 812(b)(4) criteria for placement in schedule IV 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 daridorexant as a schedule IV 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 interim final rule at *http://www.regulations.gov,* under Docket Number ''DEA–949.'' 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

Daridorexant is an NME that has not been marketed in the United States or any country; evidence regarding its diversion, illicit manufacturing, or deliberate ingestion is lacking. There are no reports of law enforcement encounters of daridorexant in the National Forensic Laboratory Information System (NFLIS) database.[2] However, daridorexant is related in action to schedule IV depressants such as suvorexant and lemborexant. It is thus reasonable to assume that daridorexant may be diverted from legitimate channels, used contrary to or without medical advice, and otherwise abused so as to create hazards to the users and to the safety of the community to an extent similar to that of schedule IV CNS depressants. In clinical studies, daridorexant produced abuse-related effects in humans similar to suvorexant and zolpidem (schedule IV sedatives) and shares pharmacological mechanism of action similar to suvorexant and lemborexant; thus, it is likely to be abused for its sedative effects contrary to medical advice.

2. Scientific Evidence of Its Pharmacological Effects, if Known

Daridorexant shares pharmacological profiles with other dual orexin receptor antagonists such as suvorexant and lemborexant, schedule IV CNS depressants. Data from the orexin binding studies demonstrated that daridorexant behaved as an insurmountable antagonist at the dual orexin receptors (OXIR and OX2R).

[2] NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. It systematically collects results from drug chemistry analyses conducted by State and local forensic laboratories. NFLIS data were queried on January 18, 2022.

Daridorexant is similar to suvorexant in its potency and duration of action at OX1R; however, it is more potent and has double the occupancy time as suvorexant at OX2R.

In animal studies, oral doses of daridorexant (100, 300, and 1000 mg/kg) produced transient decrease in rectally measured body temperature and increased incidence of whole-body tremors. Dose-dependent decline in activity was observed in unstimulated rats. In a study conducted to measure locomotor activity following daridorexant administration, rats given single oral dose of 300 mg/kg showed decline in locomotor activity when compared to the vehicle control group. Daridorexant's reinforcing properties were assessed by determining whether self-administration behavior was maintained when the drug was substituted for cocaine. Data from this study showed that rats self-administered cocaine (0.8 mg/kg/infusion), but doses of 0.1, 0.3, and 1 mg/kg/infusion of daridorexant produced a significantly lower mean number of active lever presses.

A randomized, double-blind, double-dummy, active-and placebo-controlled, 6-way cross-over study was conducted to determine the abuse potential of single oral doses of daridorexant. Suvorexant (150 mg) and Zolpidem (30 mg) served as the positive controls. Subjects received daridorexant at therapeutic (50 mg) and supratherapeutic (100 and 150 mg) doses. Bipolar visual analog scale (VAS) for Drug-Liking (0–100) served as the primary end. A score of 0 described a drug-disliking response; a score of 50 represented a neutral response, while a score of 100 described a strong drug liking. Drug liking scores following supratherapeutic doses (100 and 150 mg) of daridorexant showed statistically significant increases as compared to placebo on positive subjective measures (VAS measures for Drug Liking, Take Drug Again, Overall Drug Liking, High, and Good Drug Effects) and were statistically similar to those following suvorexant and zolpidem. Further, using a Drowsiness/Alertness VAS and an observer assessment of alertness/sedation, daridorexant's sedative properties were assessed. Both measures demonstrate that similar to suvorexant and zolpidem, daridorexant elicits drowsiness and sedation.

Data from Phase 1 clinical safety studies showed that daridorexant (5–200 mg) administered to 478 subjects produced somnolence in 52.7 percent (252), fatigue in 10.9 percent (52), and disturbances in attention in 3.8 percent (18) of subjects, respectively. Daridorexant at every dose produced somnolence at a rate that is 2- to 3-fold higher than that reported in the placebo-treated group. In two Phase 2 studies conducted to evaluate the efficacy and safety of daridorexant in subjects with insomnia disorder (one with adults (aged 18–64 years) at doses of 5–50 mg and the other with the elderly (≥65 years) at doses of 10–50 mg), daridorexant treatment led to reports of somnolence that exceeded reports of other effects that may be associated with abuse potential, including fatigue (5 (2.1 percent)) and dizziness (3 (1.3 percent). In three Phase 3 studies, which were conducted as confirmatory studies in adults and elderly subjects with insomnia disorder and were similarly designed to the two Phase 2 studies, the treatment-emergent adverse effects with the highest number of reports were somnolence (38 (2.14 percent)), fatigue (34 (1.91 percent)), and dizziness (26 (1.46 percent)). These types of reports were similar to those reported in the Phase 1 and 2 studies. The reported adverse events from the Phase 1, 2, and 3 studies demonstrate there were no significant abuse-related signals in these studies.

Daridorexant, similar to schedule IV drugs such as suvorexant and zolpidem, has sedative effects. In a human abuse potential (HAP) study, daridorexant produced abuse-related effects in humans similar to those of suvorexant and zolpidem. The abuse-related neuropharmacology profile of daridorexant is similar to that of schedule IV CNS depressants, such as suvorexant and lemborexant, and is consistent with its mechanism of action as a dual orexin receptors antagonist.

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

Daridorexant, chemically known as [(S)-2-(5-chloro-4-methyl-1*H*-benzo[*d*]imidazol-2-yl)-2-methylpyrrolidin-1-yl](5-methoxy-2-(2*H*-1,2,3-triazol-2-yl)phenyl)methanone, is an NME. It is soluble in acidic water and slightly soluble in ethanol. It has one stereoisomer with one chiral center. The drug product is manufactured in tablet dose strengths that contain 25 mg and 50 mg of the active ingredient (*i.e.,* daridorexant) and a series of excipients to aid in taste and tablet disintegration. The excipients in the tablet have no known abuse liability. Daridorexant plasma exposure is dose proportional from 25 mg to 50 mg with an absolute bioavailability of 62 percent, and has consistent pharmacokinetic profile following multiple-dose and single-dose administration with no accumulation.

As discussed in the background section, daridorexant 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 daridorexant, since it has not been marketed, legally or illegally, in the United States or any country. There is no evidence of diversion of daridorexant that has been distributed for research, such as for clinical trials. Data from preclinical and clinical studies indicate that the abuse potential of daridorexant is similar to that of schedule IV CNS depressants such as suvorexant and lemborexant. Consistent with the fact that daridorexant is an NME; NFLIS database had no records of encounters by the law enforcement.

The pharmacological mechanism of action of daridorexant as a dual orexin receptor antagonist suggests that its pattern of abuse would be similar to schedule IV depressants with a similar mechanism of action, such as suvorexant and lemborexant.

5. The Scope, Duration, and Significance of Abuse

Data from preclinical and clinical studies showed that daridorexant has an abuse potential similar to that of the schedule IV depressants such as suvorexant and zolpidem. Thus, daridorexant, similar to these schedule IV substances, will have low potential for abuse relative to drugs and substances in schedule III. A search by DEA of the NFLIS database found no evidence of law enforcement encounters of daridorexant in the United States. Because daridorexant has a mechanism of action similar to schedule IV drugs suvorexant and lemborexant, it is likely that upon availability of daridorexant in the market, it will be abused similar to these schedule IV depressants.

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

The public health risk associated with daridorexant is largely due to its abuse potential. Data from preclinical and clinical studies showed that daridorexant has abuse potential similar to that of schedule IV depressants zolpidem and suvorexant. Therefore, upon availability for marketing, it is likely to pose a public health risk to a degree similar to these schedule IV depressants. Data from clinical trials showed that daridorexant has rewarding and depressant effects. The abuse of daridorexant may present risks to the

public health at a level similar to those associated with the abuse of schedule IV CNS depressants.

7. Its Psychic or Physiological Dependence Liability

Data obtained from a HAP study demonstrate that similar to suvorexant and zolpidem, daridorexant produced subjective responses to measures such as Drug Liking, Overall Drug Liking, Good Drug Effects, High, and Take Drug Again; indicative of psychological effects. HHS states that the data suggest daridorexant can produce psychic dependence similar to zolpidem and suvorexant, schedule IV depressants.

Results from a physiologic dependence study conducted in rats demonstrate that oral doses (0, 20, or 200 mg/kg/day) of daridorexant administered for 28-days followed by a 14-days discontinuation period did not produce alterations in physiological, neurobehavioral, or locomotor parameters during the discontinuation Phase of the study. Physical dependence signs were not observed in clinical studies after discontinuation of treatment in Phase 3 studies.

Data from animal studies and clinical trials demonstrate that chronic administration of daridorexant did not produce withdrawal signs or symptoms upon discontinuation. Daridorexant does not produce physical dependence.

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

Daridorexant 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 daridorexant. As such, DEA hereby schedules daridorexant 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)(4), finds that:

(1) Daridorexant has a low potential for abuse relative to the drugs or other substances in Schedule III.

Daridorexant, similar to schedule IV depressants such as suvorexant and lemborexant, is an orexin receptor antagonist. It produced sedation in general behavioral and locomotor studies. In a HAP study, oral administration of therapeutic (50 mg) and supratherapeutic doses (100 and 150 mg) of daridorexant produced increases in positive subjective measures such as Drug Liking, Overall Drug Liking, Good Drug Effects, High, and Take Drug Again that were statistically greater than those produced by placebo. These subjective responses following daridorexant were statistically similar to those produced by the positive control drugs that are schedule IV depressant such as zolpidem and suvorexant. These data show that daridorexant has an abuse potential that is similar to the schedule IV drugs zolpidem and suvorexant. Because daridorexant is similar to suvorexant and zolpidem in its abuse potential, daridorexant has a low potential for abuse relative to the drugs or other substances in schedule III.

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

FDA recently approved the NDA for daridorexant as an oral treatment for adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance. Thus, daridorexant has a currently accepted medical use in treatment in the United States.

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

Data from both preclinical and clinical studies demonstrate that discontinuation of daridorexant was not associated with withdrawal symptoms indicative of physical dependence. Because daridorexant produced positive subjective responses in a HAP study similar to those of zolpidem and suvorexant (both schedule IV drugs), it is likely that daridorexant can produce psychic dependence to an extent that is similar to these schedule IV substances. Thus, abuse of daridorexant may lead to limited physical or psychological dependence relative to the drugs or other substances in schedule III.

Based on these findings, the Administrator concludes that daridorexant warrants control in schedule IV of the CSA. 21 U.S.C. 812(b)(4).

Requirements for Handling Daridorexant

Daridorexant is subject to the CSA's schedule IV 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 IV 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, daridorexant 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 daridorexant and is not registered with DEA must submit an application for registration and may not continue to handle daridorexant 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 daridorexant pursuant to a lawful prescription.

2. *Disposal of stocks.* Any person unwilling or unable to obtain a schedule IV registration must surrender all quantities of currently held daridorexant, or may transfer all quantities of currently held daridorexant to a person registered with DEA. Daridorexant 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.* Daridorexant 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 daridorexant 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 daridorexant pursuant to a lawful prescription.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of daridorexant 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

daridorexant must take an inventory of daridorexant 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 daridorexant must take an initial inventory of all stocks of controlled substances (including daridorexant) 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 daridorexant) 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 daridorexant pursuant to a lawful prescription.

6. *Records and Reports.* DEA registrants must maintain records and submit reports for daridorexant, 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 daridorexant, or products containing daridorexant, 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 IV controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of daridorexant may only be for the legitimate purposes consistent with the drug's labeling, or for research activities authorized by the Federal Food, Drug, and Cosmetic Act (FDCA), as applicable, and the CSA.

9. *Importation and Exportation.* All importation and exportation of daridorexant 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 daridorexant 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 any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

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 § 1308.14:
■ a. Redesignate paragraphs (c)(16) through (58) as (c)(17) through (59); and
■ b. Add new paragraph (c)(16).
■ The addition reads as follows:

§ 1308.14 Schedule IV.

* * * * *

(c) * * *

(16) Daridorexant	2410

* * * * *

Anne Milgram,

Administrator.

[FR Doc. 2022–07322 Filed 4–6–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–491]

Schedules of Controlled Substances: Placement of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: By this rule, the Drug Enforcement Administration permanently places five synthetic cannabinoids, as identified in this final rule, in schedule I of the Controlled Substances Act. These five 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, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle these five specified controlled substances will continue to apply.

DATES: Effective April 7, 2022.

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

SUPPLEMENTARY INFORMATION:

In this final rule, the Drug Enforcement Administration (DEA) is permanently scheduling the following five controlled substances in schedule I of the Controlled Substances Act (CSA), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- Ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: 5F-EDMB-PINACA),
- Methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate (other names: 5F-MDMB-PICA; 5F-MDMB-2201),
- *N*-(Adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (other names: FUB-AKB48; FUB-APINACA; AKB48 *N*-(4-fluorobenzyl)),
- 1-(5-Fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (other names: 5F-CUMYL-PINACA; SGT-25), and
- (1-(4-Fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (other name: FUB-144).

Legal Authority

The CSA provides that issuing, amending, or repealing of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS); [1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). The then-Acting Administrator of DEA (as delegated by the Attorney General to the Administrator of DEA) initiated this action on his own motion, and is supported by, *inter alia,* a recommendation from the then-Acting Assistant Secretary for Health of HHS and an evaluation of all relevant data by DEA. The regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles (manufactures, distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) or proposes to handle 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 will continue to apply as a result of this action.

[1] As set forth 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 CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 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.

Background

On April 16, 2019, DEA published an order in the **Federal Register** amending 21 CFR 1308.11(h) to temporarily place ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-EDMB-PINACA); methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-MDMB-PICA); *N*-(adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (trivial names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-FLUOROBENZYL)); 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (trivial names: 5F-CUMYL-PINACA; SGT-25); and (1-(4-fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (trivial name: FUB-144) in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 84 FR 15505. That temporary scheduling order took effect on the date of publication, and was based on findings by the then-Acting Administrator of DEA that the temporary scheduling of these five synthetic cannabinoids (SCs) was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1).

On March 30, 2021, DEA published a notice of proposed rulemaking (NPRM) in the **Federal Register** to permanently control the five SCs in schedule I of the CSA. 86 FR 16553. On March 31, 2021, DEA published an order to extend the temporary scheduling of the five SCs by one year, until April 16, 2022. 86 FR 16669.

DEA and HHS Eight Factor Analyses

On February 26, 2021, HHS provided DEA with a scientific and medical evaluation and scheduling recommendation, prepared by the Food and Drug Administration (FDA), entitled ''Basis for the Recommendation to Place Ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-EDMB-PINACA]; methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate [5F-MDMB-PICA]; *N*-(adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide [FUB-AKB48;FUB-APINACA; AKB48 *N*-(4-fluorobenzyl)]; 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide [5F-CUMYL-PINACA; SGT-25]; and (1-(4-fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone [FUB-144; FUB-UR-144] and Their Salts, Isomers, and Salts of Isomers in Schedule I of the Controlled Substances Act.''

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

May 5, 2022

(X) ACTION/DECISION
( ) INFORMATION

I. TITLE: Request for Placement of Butonitazene, Etodesnitazene, Flunitazene, Metodesnitazene, Metonitazene, N-Pyrrolidino etonitazene, and Protonitazene in Schedule I for Controlled Substances in South Carolina

II. SUBJECT: Placement of Butonitazene, Etodesnitazene, Flunitazene, Metodesnitazene, Metonitazene, N-Pyrrolidino etonitazene, and Protonitazene in Schedule I for Controlled Substances

III. FACTS:

Controlled substances are governed by the South Carolina Controlled Substances Act ("CSA"), 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 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 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 April 12, 2022, the Administrator of the Drug Enforcement Administration ("DEA") issued a temporary order to schedule seven synthetic benzimidazole-opioid substances, Butonitazene, Etodesnitazene, Flunitazene, Metodesnitazene, Metonitazene, N-Pyrrolidino etonitazene, and Protonitazene, in schedule I of the Controlled Substances Act ("CSA"). This action is based on a finding by the Administrator that the placement of these seven substances in schedule I is necessary to avoid imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions

applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle these seven specified controlled substances. This final rule was published with an effective date of April 12, 2022, *Federal Register*, Volume 87, Number 70, pages 21556-21561; *https://www.govinfo.gov/content/pkg/FR-2022-04-12/pdf/2022-07640.pdf.*

IV. ANALYSIS:

To find that temporarily placing a substance in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator must consider three of the eight factors set forth in 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any risk there is to the public health. 21 U.S.C. 811(h)(3). This consideration includes any information indicating actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution of these substances. 21 U.S.C. 811(h)(3). Substances meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I have high potential for abuse, no currently accepted medical use in treatment in the United States, and no accepted safety for use under medical supervision.

The United States currently is experiencing an opioid overdose epidemic, and the presence of synthetic opioids on the illicit drug market threatens to exacerbate this. The trafficking, continued evolution, and abuse of new synthetic opioids are deadly trends posing imminent hazards to public safety. Adverse health effects associated with abuse of synthetic opioids and increased popularity of these substances have been serious concerns in recent years.Butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, N-pyrrolidino etonitazene, and protonitazene are synthetic opioids recently identified on the illicit drug market in the United States.

Data obtained from preclinical pharmacology studies show that butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, N-pyrrolidino etonitazene, and protonitazene have pharmacological profiles similar to those of the potent benzimidazole-opioids etonitazene and isotonitazene, both schedule I controlled substances. Because of their pharmacological similarities, use of these seven benzimidazole-opioid substances presents a high risk of abuse and may negatively affect users and communities.

Available data and information for butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, N-pyrrolidino etonitazene, and protonitazene indicate that these substances have high potential for abuse, no currently accepted medical use in treatment in the United States, and lack of accepted safety for use under medical supervision.

In accordance with 21 U.S.C. 811(h)(1) and (3), the Administrator considered available data and information, set forth the grounds for her determination that it is necessary to temporarily place butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, N-pyrrolidino etonitazene, and protonitazene in schedule I of the CSA and finds that such placement is necessary to avoid an imminent hazard to the public safety.

V. RECOMMENDATION:

Pursuant to S.C. Code Section 44-53-160(C), the Department recommends placing Butonitazene, Etodesnitazene, Flunitazene, Metodesnitazene, Metonitazene, N-Pyrrolidino etonitazene, and Protonitazene in Schedule I in the same manner as the federal Drug Enforcement Administration. The

listing includes their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, to Schedule I for controlled substances in South Carolina and the amendment of Section 44-53-190(B) of the South Carolina Controlled Substances Act to include:

( ) 2-(2-(4-butoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)-N,N-diethylethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (Other name: butonitazene)

( ) 2-(2-(4-ethoxybenzyl)-1H-benzimidazol-1-yl)-N,N-diethylethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (Other names: etodesnitazene; etazene)

( ) N,N-diethyl-2-(2-(4-fluorobenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (Other name: flunitazene)

( ) N,N-diethyl-2-(2-(4-methoxybenzyl)-1H-benzimidazol-1-yl)ethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (Other name: metodesnitazene)

( ) N,N-diethyl-2-(2-(4-methoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1- amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (Other name: metonitazene)

( ) 2-(4-ethoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzimidazole, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (Other names: N-pyrrolidino etonitazene; etonitazepyne)

( ) N,N-diethyl-2-(5-nitro-2-(4-propoxybenzyl)-1H-benzimidazol-1-yl)ethan-1- amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (Other name: protonitazene)

Submitted by:

Lisa Thomson
Director, Bureau of Drug Control

Gwen Thompson
Director for Healthcare Quality

Attachment:
Federal Register, Volume 87, Number 70, April 12, 2022

Matthew S. Borman,
Deputy Assistant Secretary for Export Administration.

[FR Doc. 2022–07836 Filed 4–8–22; 8:45 am]
BILLING CODE 3510–33–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–900]

Schedules of Controlled Substances: Temporary Placement of Butonitazene, Etodesnitazene, Flunitazene, Metodesnitazene, Metonitazene, *N*-Pyrrolidino etonitazene, and Protonitazene in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary amendment; temporary scheduling order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this temporary order to schedule seven synthetic benzimidazole-opioid substances, as identified in this order, in schedule I of the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of these seven substances in schedule I is necessary to avoid imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle these seven specified controlled substances.

DATES: This temporary scheduling order is effective April 12, 2022, until April 12, 2024. If this order is extended or made permanent, DEA will publish a document in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Ph.D., Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION: The Drug Enforcement Administration (DEA) issues a temporary scheduling order [1] (in the form of a temporary amendment) to add the following seven substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, to schedule I under the Controlled Substances Act (CSA):

- 2-(2-(4-butoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)-*N*,*N*-diethylethan-1-amine (butonitazene),
- 2-(2-(4-ethoxybenzyl)-1*H*-benzimidazol-1-yl)-*N*,*N*-diethylethan-1-amine (etodesnitazene; etazene),
- *N*,*N*-diethyl-2-(2-(4-fluorobenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine (flunitazene),
- *N*,*N*-diethyl-2-(2-(4-methoxybenzyl)-1*H*-benzimidazol-1-yl)ethan-1-amine (metodesnitazene),
- *N*,*N*-diethyl-2-(2-(4-methoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine (metonitazene),
- 2-(4-ethoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1*H*-benzimidazole (*N*-pyrrolidino etonitazene; etonitazepyne), and
- *N*,*N*-diethyl-2-(5-nitro-2-(4-propoxybenzyl)-1*H*-benzimidazol-1-yl)ethan-1-amine (protonitazene).

Legal Authority

The CSA provides the Attorney General (as delegated to the Administrator of DEA (Administrator) pursuant to 28 CFR 0.100) with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b), if the Administrator finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled under section 811(h), the Administrator may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under 21 U.S.C. 812, and if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308.

Background

The CSA requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of an intent to place a substance in schedule I of the CSA temporarily (*i.e.,* to issue a temporary scheduling order). 21 U.S.C. 811(h)(4). The then-Acting Administrator transmitted the required notice to the Assistant Secretary for Health of HHS (Assistant Secretary),[2] by letter dated June 16, 2021, regarding butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, and protonitazene. In a subsequent letter dated August 25, 2021, the Administrator transmitted the required notice to the Assistant Secretary regarding *N*-pyrrolidino etonitazene. The Assistant Secretary responded to these notices by letters dated July 7 and September 10, 2021, and advised that, based on a review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications (INDs) or approved new drug applications (NDAs) for butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene. The Assistant Secretary also stated that HHS had no objection to the temporary placement of these substances in schedule I of the CSA.

DEA has taken into consideration the Assistant Secretary's comments as required by subsection 811(h)(4). Butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene currently are not listed in any schedule under the CSA, and no exemptions or approvals under 21 U.S.C. 355 are in effect for these seven benzimidazole-opioids. DEA has found that the control of these seven benzimidazole-opioids in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety.

As required by 21 U.S.C. 811(h)(1)(A), DEA published a notice of intent (NoI) to temporarily schedule butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene on December 7, 2021. 86 FR 69182. That NoI discussed findings from DEA's three-factor analysis dated November 2021, which DEA made available on *www.regulations.gov*.

To find that temporarily placing a substance in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator must consider three of the eight factors set forth in 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any,

[1] Though DEA has used the term ''final order'' with respect to temporary scheduling orders in the past, this order adheres to the statutory language of 21 U.S.C. 811(h), which refers to a ''temporary scheduling order.'' No substantive change is intended.

[2] 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.

risk there is to the public health. 21 U.S.C. 811(h)(3). This consideration includes any information indicating actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution of these substances. 21 U.S.C. 811(h)(3).

Substances meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I have high potential for abuse, no currently accepted medical use in treatment in the United States, and no accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1). DEA's November 2021 three-factor analysis and the Assistant Secretary's July 7 and September 10, 2021, letters are available in their entirety under the tab ''Supporting Documents'' of the public docket of this action at *www.regulations.gov*.

Since the publication of the NoI, DEA discovered that the NoI inadvertently assigned duplicate drug codes to butonitazene, etodesnitazene, flunitazene, and protonitazene. Accordingly, with this temporary scheduling order, DEA hereby corrects those errors by assigning new drug codes to all seven substances: butonitazene (9751), etodesnitazene (9765), flunitazene (9756), metodesnitazene (9764), metonitazene (9757), *N*-pyrrolidino etonitazene (9758), and protonitazene (9759).

Seven Benzimidazole-Opioids: Butonitazene, Etodesnitazene, Flunitazene, Metodesnitazene, Metonitazene, *N*-Pyrrolidino Etonitazene, and Protonitazene

The United States currently is experiencing an opioid overdose epidemic, and the presence of synthetic opioids on the illicit drug market threatens to exacerbate this. The trafficking, continued evolution, and abuse of new synthetic opioids are deadly trends posing imminent hazards to public safety. Adverse health effects associated with abuse of synthetic opioids and increased popularity of these substances have been serious concerns in recent years. Butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene are synthetic opioids recently identified on the illicit drug market in the United States.

Data obtained from preclinical pharmacology studies show that butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene have pharmacological profiles similar to those of the potent benzimidazole-opioids etonitazene and isotonitazene, both schedule I controlled substances. Because of their pharmacological similarities, use of these seven benzimidazole-opioid substances presents a high risk of abuse and may negatively affect users and communities. They have been identified in at least 44 toxicology and post-mortem cases in the United States between November 2020 and July 2021. Specifically, butonitazene has been identified in one case, etodesnitazene in five cases, flunitazene in four cases, metodesnitazene in one case, metonitazene in 20 cases, *N*-pyrrolidino etonitazene in eight cases, and protonitazene in five cases, which together create serious public safety concerns.

Available data and information for butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene, summarized below, indicate that these substances have high potential for abuse, no currently accepted medical use in treatment in the United States, and lack of accepted safety for use under medical supervision. DEA's three-factor analysis is available in its entirety under ''Supporting and Related Material'' of the public docket for this action at *www.regulations.gov* under Docket Number DEA–900.

Factor 4. History and Current Pattern of Abuse

In the late 1950s, pharmaceutical research laboratories of the Swiss chemical company CIBA Aktiengesellschaft synthesized a group of benzimidazole derivatives with analgesic properties; however, the research did not lead to any medically approved analgesic products. These benzimidazole derivatives include schedule I substances such as synthetic opioids clonitazene, etonitazene, and isotonitazene. In 2019, isotonitazene emerged on the illicit drug market and was involved in numerous fatal overdose events. In August 2020, DEA temporarily controlled it as a schedule I substance under the CSA (85 FR 51342).

Subsequently, the benzimidazole-opioids at issue here have emerged on the illicit drug market. Law enforcement agencies have encountered etodesnitazene, flunitazene, metonitazene, and protonitazene in several solid (*e.g.,* powder and rock) and liquid forms. These substances are not approved for medical use anywhere in the world. The Assistant Secretary, by letters dated July 7 and September 10, 2021, informed DEA that there are no FDA-approved NDAs or INDs for them in the United States. Hence, there are no legitimate channels for these substances as marketed drug products. Their appearance on the illicit drug market is similar to other synthetic opioids trafficked for their psychoactive effects. These seven opioid substances are likely to be abused in the same manner as schedule I opioids such as etonitazene, isotonitazene, and heroin. They have been identified as white to beige powders or in liquid forms, typically of unknown purity or concentration.

In 2020 and 2021, butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, and protonitazene emerged on the illicit synthetic drug market as evidenced by their identification in forensic drug seizures or biological samples. In July 2020, metonitazene was first seized as a white powdery substance in a North Carolina case. Based on data from the National Forensic Laboratory Information System (NFLIS),[3] law enforcement often encounters etodesnitazene, flunitazene, metonitazene, and protonitazene in mixtures. Substances found in combination with some of these benzimidazole-opioids include cutting agents (caffeine, xylazine, etc.) or other substances of abuse such as heroin, fentanyl (schedule II), fentanyl analogs, and tramadol (schedule IV).

In the United States, butonitazene, etodesnitazene, flunitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene have been identified alone or in combination with other substances such as designer benzodiazepines and fentanyl (see Factors 5 and 6). Evidence suggests that individuals are using these substances as a replacement for other opioids, either knowingly or unknowingly. Information gathered from case histories and autopsy findings show that deaths involving metonitazene were similar to those of opioid-related deaths. Identified material or paraphernalia from death-scene investigations also were consistent with opioid use. These seven substances are likely to be abused in the same manner as schedule I

[3] NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS 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.

opioids such as isotonitazene and heroin.

Factor 5. Scope, Duration, and Significance of Abuse

Butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene are synthetic opioids, and evidence suggests they are abused for their opioidergic effects (see Factor 6). Their abuse has resulted in their identification in toxicology and post-mortem cases. Between January and February 2021, metonitazene has been positively identified in 20 forensic post-mortem cases from seven different states: Tennessee (10), Illinois (5), Florida (1), Iowa (1), Ohio (1), South Carolina (1), and Wisconsin (1). Most (18) of the decedents were male, with ages ranging from 19 to 63 years and an average age of 41 years. Metonitazene was identified as the sole drug detected in only three cases, and the only opioid in six cases.

Detection of *N*-pyrrolidino etonitazene in a toxicology case first was reported [4] in May 2021. It has been identified in a total of eight post-mortem cases from five different states (Colorado (1), Florida (1), New York (1), Pennsylvania (1), and West Virginia (4)) between January and April 2021. The decedents' ages spanned their 20s to 50s. *N*-Pyrrolidino etonitazene was the only drug of interest in one of these cases. In the other cases, it was co-identified with designer benzodiazepines (7), fentanyl (4), and methamphetamine (4).

Data from law enforcement encounters suggests that etodesnitazene, flunitazene, metonitazene, butonitazene, *N*-pyrrolidino etonitazene, and protonitazene are abused [5] in the United States as recreational drugs. Law enforcement encounters of etodesnitazene, flunitazene, metonitazene, butonitazene, *N*-pyrrolidino etonitazene, and protonitazene as reported to NFLIS (Federal, State, and local laboratories) include 417 exhibits since 2020 (queried 11/23/2021). NFLIS registered two encounters of etodesnitazene from two states, five encounters of flunitazene from four states, 399 encounters of metonitazene from eighteen states, three encounters of butonitazene from one state, five encounters of *N*-pyrrolidino etonitazene from three states, and three encounters of protonitazene from three states. Data from NFLIS show that at least 561.55 grams of metonitazene has been encountered by law enforcement since 2020, and it was often suspected as heroin or fentanyl. This suggests that metonitazene might be presented as a substitute for heroin or fentanyl and likely abused in the same manner as either of these substances. The lack of identification of metodesnitazene in law enforcement reports might be due to the rapid appearance of these benzimidazole-opioids and under-reporting as forensic laboratories try to secure reference standards for these substances. However, metodesnitazene has been identified in toxicology cases.

The population likely to abuse these seven benzimidazole-opioids appears to be the same as those abusing other opioid substances such as heroin, tramadol, fentanyl, and other synthetic opioids. This is evidenced by the types of other drugs co-identified in biological samples and law enforcement encounters. Because abusers are likely to obtain these substances through unregulated sources, their identity, purity, and quantity are uncertain and likely to be inconsistent, thus posing significant adverse health risks to the end user. The misuse and abuse of opioids have been demonstrated and are well- characterized. According to the most recent data from the National Survey on Drug Use and Health (NSDUH),[6] as of 2019, an estimated 10.1 million people aged 12 years or older misused opioids in the past year, including 9.7 million prescription pain reliever misusers and 745,000 heroin users. In 2019, an estimated 1.6 million people had an opioid use disorder, including 1.4 million people with a prescription pain reliever use disorder and 438,000 people with heroin use disorder. This population likely is at risk of abusing butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene. Individuals who initiate (*i.e.,* use a drug for the first time) use of these benzimidazole-opioids are likely to be at risk of developing substance use disorder, overdose, and death similar to that of other opioid analgesics (*e.g.,* fentanyl, morphine, etc.). Law enforcement or toxicology reports demonstrate that the seven substances at issue are being distributed illicitly and abused.

Factor 6. What, if Any, Risk There Is to the Public Health

The increase in opioid overdose deaths in the United States has been exacerbated recently by the availability of potent synthetic opioids on the illicit drug market. Data obtained from pre-clinical studies demonstrate that butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene exhibit pharmacological profiles similar to that of schedule I substances such as etonitazene, isotonitazene, and other mu-opioid receptor agonists. These seven benzimidazole-opioids bind to and act as agonists at the mu-opioid receptors. It is well established that substances that act as mu-opioid receptor agonists have a high potential for abuse and addiction and can induce dose-dependent respiratory depression.

As with any mu-opioid receptor agonist, the potential health and safety risks for users of butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene are high. Consistently, these substances have been identified in toxicology cases. The public health risks attendant to the abuse of mu-opioid receptor agonists are well established. These risks include large numbers of drug treatment admissions, emergency department visits, and fatal overdoses. According to the Centers for Disease Control and Prevention (CDC), opioids, mainly synthetic opioids other than methadone, are predominantly responsible for drug overdose deaths in recent years. According to CDC data, synthetic opioid-related overdose deaths in the United States increased from 36,359 in 2019, to 56,688 in 2020 (CDC, 2021).[7] Of the drug overdose death data (70,630) for 2019, synthetic opioids were involved in about 51.4 percent

[4] Center for Forensic Science Research and Education. Public Alert: New High Potency Synthetic Opioid *N*-Pyrrolidino Etonitazene (Etonitazepyne) Linked to Overdoses across United States. June 17, 2021.

[5] While law enforcement data are not direct evidence of abuse, they can lead to an inference that drugs have been diverted and abused. *See* 76 FR 77330, 77332, Dec. 12, 2011.

[6] NSDUH, formerly known as the National Household Survey on Drug Abuse (NHSDA), is conducted annually by the Department of Health and Human Services' Substance Abuse and Mental Health Services Administration (SAMHSA). It is the primary source of estimates of the prevalence and incidence of non-medical use of pharmaceutical drugs, illicit drugs, alcohol, and tobacco use in the United States. The survey is based on a nationally representative sample of the civilian, non-institutionalized population 12 years of age and older. The survey excludes homeless people who do not use shelters, active military personnel, and residents of institutional group quarters such as jails and hospitals. The NSDUH provides yearly national and state level estimates of drug abuse, and includes prevalence estimates by lifetime (*i.e.,* ever used), past year, and past month abuse or dependence. The 2019 NSDUH Annual Report. (Last accessed July 26, 2021).

[7] 12 Month-ending (April, 2021) Provisional Number of Drug Overdose Deaths. Reported provisional data as of November 7, 2021. *https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.*

(36,359) of all drug-involved overdose deaths.

According to a recent publication, since November 2020, there has been an increase in metonitazene-related adverse events, including deaths.[8] Metonitazene has been co-identified with other substances in biological samples from 20 post-mortem cases from seven different states: Florida (1), Illinois (5), Iowa (1), Ohio (1), South Carolina (1), Tennessee (10), and Wisconsin (1). Information gathered from case histories and autopsy findings show that deaths involving metonitazene were similar to those of opioid-related deaths. Identified material or paraphernalia from death-scene investigations were consistent with opioid use. Reports obtained from autopsy findings showed that deaths involving metonitazene presented pulmonary and cerebral edema, as well as distended bladder and signs of intravenous drug use. Of the cases for which death certificate data were available, metonitazene was reported as a cause of death in four cases, of which three cases listed metonitazene as the only cause.

According to recent reports, butonitazene (1 instance), etodesnitazene (11), flunitazene (4), metodesnitazene (1), metonitazene (43), protonitazene (10), and *N*-pyrrolidino etonitazene (16) have been identified in toxicology cases in the United States.[9] For some cases involving *N*-pyrrolidino etonitazene, it was co-identified with fentanyl in four cases and with novel benzodiazepines (*e.g.,* flualprazolam, etizolam, and clonazolam) in six others.

Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information summarized above, the uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene pose an imminent hazard to the public safety. DEA is not aware of any currently accepted medical uses for these substances in the United States. A substance meeting the statutory requirements for temporary scheduling, found in 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I must have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene indicate that these substances meet the three statutory criteria. As required by 21 U.S.C. 811(h)(4), the then-Acting Administrator transmitted to the Assistant Secretary for Health, via letter dated June 16, 2021, notice of his intent to temporarily place butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, and protonitazene in schedule I. In a letter to the Assistant Secretary for Health dated August 25, 2021, the Administrator transmitted notice of her intent to temporarily place *N*-pyrrolidino etonitazene in schedule I. DEA subsequently published a NoI on December 7, 2021. 86 FR 69182.

Conclusion

In accordance with 21 U.S.C. 811(h)(1) and (3), the Administrator considered available data and information, herein set forth the grounds for her determination that it is necessary to temporarily place butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene in schedule I of the CSA and finds that such placement is necessary to avoid an imminent hazard to the public safety.

This temporary order scheduling these substances will be effective on the date the order is published in the **Federal Register** and remain in effect for two years, with a possible extension of one year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2).

The CSA sets forth specific criteria for scheduling drugs or other substances. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures ''on the record after opportunity for a hearing'' conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties appropriate process and the government any additional relevant information needed to make determinations. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Requirements for Handling

Upon the effective date of this temporary order, butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, and possession of, and engagement in research and conduct of instructional activities or chemical analysis with, schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (possesses, manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with) or desires to handle, butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene 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, as of April 12, 2022. Any person who currently handles butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene and is not registered with DEA must submit an application for registration and may not continue to handle butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene as of April 12, 2022, unless DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of these substances in a manner not authorized by the CSA on or after April 12, 2022 is unlawful, and those in possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is unable to obtain a schedule I registration to handle butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene must

[8] Krotulski A.J, Papsun D.M, Walton S.E, Logan B.K. Metonitazene in the United States-Forensic toxicology assessment of a potent new synthetic opioid using liquid chromatography mass spectrometry. Drug Test Anal. 2021 Jun 16.

[9] Center for Forensic Science Research and Education. NPS Opioids in the United States—Trend Report Q1, Q2, and Q3, 2021.

surrender all currently held quantities of these seven substances.

3. *Security.* Butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and 871(b), and in accordance with 21 CFR 1301.71–1301.76, as of April 12, 2022. Non-practitioners handling these seven substances must also 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 butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene must comply with 21 U.S.C. 825 and 958(e) and 21 CFR part 1302. Current DEA registrants will have 30 calendar days from April 12, 2022 to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene on the effective date of this order must take an inventory of all stocks of these substances on hand pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants will have 30 calendar days from the effective date of this order to comply with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene) on hand on a biennial basis pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records.* All DEA registrants must maintain records with respect to butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR parts 1304, 1312, and 1317, and section 1307.11. Current DEA registrants authorized to handle these seven substances shall have 30 calendar days from the effective date of this order to comply with all recordkeeping requirements.

7. *Reports.* All DEA registrants must submit reports with respect to butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304, 1312, and 1317, and sections 1301.74(c) and 1301.76(b), as of April 12, 2022. Manufacturers and distributors must also submit reports regarding these seven substances 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.* All DEA registrants who distribute butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of April 12, 2022.

9. *Importation and Exportation.* All importation and exportation of butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312 as of April 12, 2022.

10. *Quota.* Only DEA-registered manufacturers may manufacture butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303, as of April 12, 2022.

11. *Liability.* Any activity involving butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, *N*-pyrrolidino etonitazene, and protonitazene not authorized by or in violation of the CSA, occurring as of April 12, 2022, is unlawful and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

The CSA provides for expedited temporary scheduling actions where necessary to avoid imminent hazards to the public safety. Under 21 U.S.C. 811(h), the Administrator, as delegated by the Attorney General, may, by order, temporarily place substances in schedule I. Such orders may not be issued before the expiration of 30 days from: (1) The publication of a notice in the **Federal Register** of the intent to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary for Health of HHS, as delegated by the Secretary of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as section 811(h) directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, including the requirement to publish in the **Federal Register** a Notice of Intent, the notice-and-comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this temporary scheduling order. The APA expressly differentiates between orders and rules, as it defines an ''order'' to mean a ''final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency *in a matter other than rule making.*'' 5 U.S.C. 551(6) (emphasis added). The specific language chosen by Congress indicates its intent that DEA issue *orders* instead of proceeding by rulemaking when temporarily scheduling substances. Given that Congress specifically requires the Administrator (as delegated by the Attorney General) to follow rulemaking procedures for *other* kinds of scheduling actions, *see* 21 U.S.C. 811(a), it is noteworthy that, in section 811(h), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

Alternatively, even if this action was subject to section 553 of the APA, the Administrator finds that there is good cause to forgo its notice-and-comment requirements, as any further delays in the process for issuing temporary scheduling orders would be impracticable and contrary to the public interest given the manifest urgency to avoid imminent hazards to public safety.

Although DEA believes this temporary scheduling order is not subject to the notice-and-comment requirements of section 553 of the APA, DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Administrator took into consideration comments submitted by the Assistant Secretary in response to the notices that DEA transmitted to the Assistant Secretary pursuant to such subsection.

Further, DEA believes that this temporary scheduling action is not a ''rule'' as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

In accordance with the principles of Executive Orders (E.O.) 12866 and 13563, this action is not a significant regulatory action. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866 classifies a ''significant regulatory action,'' requiring review by the Office of Management and Budget, as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O. Because this is not a rulemaking action, this is not a significant regulatory action as defined in Section 3(f) of E.O. 12866.

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 13132 (Federalism), it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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 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 paragraphs (h)(50) through (h)(56) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

Anne Milgram,

Administrator.

[FR Doc. 2022–07640 Filed 4–11–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 938

[SATS No. PA–161–FOR; Docket ID: OSM–2012–0009; S1D1S SS08011000 SX064A000 221S180110; S2D2S SS08011000 SX064A000 22XS501520]

Pennsylvania Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are approving an amendment to the approved Pennsylvania regulatory program (the Pennsylvania program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The amendment we are approving consists of revisions and additions to Pennsylvania's regulations related to beneficial use of coal ash at active surface coal mining sites.

DATES: The effective date is May 12, 2022.

FOR FURTHER INFORMATION CONTACT: Mr. Ben Owens, Acting Field Office Director, Pittsburgh Field Office, Telephone: (412) 937–2857; email: *bowens@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Pennsylvania Program and Federal Regulation of Coal Combustion Residues

The Pennsylvania Program

Section 503(a) of the SMCRA permits a state to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Pennsylvania program effective July 30, 1982. You can find background information on the Pennsylvania program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Pennsylvania program in the July 30, 1982, **Federal Register** (47 FR 33050). You can also find later actions