Veolia North America - Industrial Business Regulatory Update - March 2020

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A. EPA Announces Enforcement Discretion Policy for COVID-19 Pandemic

Agency

Environmental Protection Agency (EPA)

Dates

Published Date: 03/26/2020
Effective Date: 03/13/2020 (this was applied retroactively)

Summary

The Environmental Protection Agency has released a memo outlining an Enforcement Discretion Policy in response to the COVID-19 Pandemic. The EPA expects all regulated entities to continue to manage and operate their facilities in compliance with their permits and regulations and in a manner that is safe and that protects the public and the environment. The EPA has issued this temporary policy to apply to noncompliance in lieu of an otherwise applicable EPA enforcement response policy. The EPA stated they are cognizant of potential worker shortages and social distancing restrictions imposed by both governments and corporations or recommendations by the Centers for Disease Control and Prevention.

The EPA will post updates as well as the date for termination of this policy at the following website at least seven days prior to rescinding this policy:

https://www.epa.gov/enforcement/enforcement-policy-guidance-publications

Facilities should contact the appropriate implementing authority (EPA region, authorized state, or tribe) if facility operations impacted by the COVID-19 pandemic may create an acute risk or an imminent threat to human health or the environment. Even in authorized programs, it is recommended for facilities, states, and tribes to consult with their EPA regional office on acute risks and imminent threats. If an entity contacts the EPA due to noncompliance that could result in an acute risk or an imminent threat to human health or the environment, the EPA will act as follows.

1. If there is an authorized program, the EPA's first step will be to consult with the state or tribe, to discuss measures to reduce or stop the acute or imminent threat to health or the environment from the COVID-19-caused noncompliance. Consultation with authorized states or tribes will proceed in accordance with the July 11, 2019 memorandum on Enhancing Effective Partnerships Between EPA and States in Civil Enforcement and Compliance Assurance Work.
2. In cases where the EPA implements the program directly:
    a. The EPA regional office plans to evaluate whether an applicable permit, statutory, or regulatory provision addresses the situation. The EPA's Office of Enforcement and Compliance Assurance (OECA) will work with program offices on nationwide issues that may arise.
    b. If there is no permit/regulatory provision that addresses the situation, the EPA will work with the facility to minimize or prevent the acute or imminent threat to health or the environment from the COVID-19-caused noncompliance and obtain a return to compliance as soon as possible.

c. The EPA will also inform the relevant state or tribe of any acute threats and actions taken in response to the noncompliance.
d. The EPA will consider the circumstances, including the COVID-19 pandemic, when determining whether an enforcement response is appropriate.

If a facility suffers from failure of air emission control or wastewater or waste treatment systems or other facility equipment that may result in exceedances of enforceable limitations on emissions to air or discharges to water, or land disposal, or other unauthorized releases, the facility should notify the implementing authority (EPA regional office or authorized state or tribe) as quickly as possible. The notification also should include information on the pollutants emitted, discharged, discarded, or released; the comparison between the expected emissions or discharges, disposal, or release and any applicable limitation(s); and the expected duration and timing of the exceedance(s) or releases. The EPA will consult with authorized states or tribes, as applicable, in accordance with the July 11, 2019 memorandum on Enhancing Effective Partnerships Between EPA and States in Civil Enforcement and Compliance Assurance Work to determine the appropriate response. Where the EPA implements the program directly, the EPA will evaluate whether the risk posed by the exceedance, disposal, or release is acute or may create an imminent threat to human health or the environment and will follow the steps stated above.

If facility operations resulting in noncompliance are not already addressed by the EPA above, regulated entities should take the steps identified under Part I.A. of the memo. Part I.A. explains that entities should make every effort to comply with their environmental compliance obligations. Secondly, when compliance is not reasonably practicable, facilities should act responsibly under the circumstances to minimize the effects and duration of noncompliance caused by COVID-19. Additionally, the facility should identify the specific nature and dates of the noncompliance and be able to identify how COVID-19 was the cause of noncompliance. The facility must document the decisions and actions taken in response, including best efforts to comply. The EPA will consider the circumstances, when determining whether enforcement response is appropriate.

If a facility is a GENERATOR of hazardous waste and, due to disruptions caused by the COVID-19 pandemic, is unable to transfer the waste off-site within the time periods required under RCRA to maintain its generator status, the facility should continue to properly label and store such waste and take the steps identified under Part I.A, above.

The required time periods for the federal level are as follows:

- Very Small Quantity Generators (VSQG): None
- Small Quantity Generators (SQG): ≤180 days or ≤270 days (if transporting greater than 200 miles)
- Large Quantity Generators (LQG): ≤90 days

**These time periods may vary by state.

In addition, as an exercise of enforcement discretion, the EPA will treat Very Small Quantity Generators and Small Quantity Generators as retaining that status, even if the amount of hazardous waste stored on site exceeds a regulatory volume threshold due to the generator's inability to arrange for shipping of hazardous waste off of the generator's site due to the COVID-19 pandemic.

This policy does not apply to criminal activity (willful violations.) This policy does not apply to superfund or RCRA Corrective Action enforcement instruments. This policy does not apply to imports.

It is important to note that State agencies may choose to adopt or reject any EPA regulations that are less stringent than what the State enforces. For example, Basil Seggos, commissioner of New York's Department of Environmental Conservation, has strong beliefs against this enforcement discretion policy and has stated that New York will continue to enforce the environmental regulations. California and Maryland have taken similar positions. It is vital, as always, to research individual State agencies policies to determine if the State agrees with EPA's position and approach.

Reference/Link

The link below will allow you to view/print this memo.

https://www.epa.gov/sites/production/files/2020-03/documents/oecamemooncovid19implications.pdf

B. Hazardous Waste Electronic Manifest System ("e-Manifest") Advisory Board; Revised Notice of Public Meeting

Agency

Environmental Protection Agency (EPA)

Dates

Published Date: 03/27/2020
Meeting Dates: April 14–16, 2020, from approximately 10:00 a.m. to 6:00 p.m. (EDT)

Summary

The Environmental Protection Agency has decided to move the Hazardous Waste Electronic Manifest System Public Meeting to a three day virtual public meeting (held remotely via webcast and phone.) The purpose of this meeting is to seek the Board's and stakeholder's consultation and recommendations regarding the e-Manifest system. The meeting theme is "Reengineering Electronic Signatures for Generators and Transporters to Increase Adoption of Electronic Manifests."

The meeting will still be held from approximately 10:00 am to 6:00 pm ET on April 14-16, 2020. Please refer to the e-Manifest website at www.epa.gov/e-manifest for information on how to access the live webcasting of this public meeting.

Both oral comments and written comments will take place during the meeting. When possible, public comments will be taken in advance. To ensure proper receipt of your public comments by the EPA, it is imperative that you identify docket ID number EPA–HQ–OLEM–2020–0075. Comments must be submitted to the EPA by April 7, 2020. To the extent that time permits, interested persons who have not pre-registered may be permitted by the e-Manifest Advisory Board Chair to present oral comments during the virtual meeting at the designated time on the agenda.

Reference/Link

The link below will allow you to view/print this revised notice.

https://www.govinfo.gov/content/pkg/FR-2020-03-27/pdf/2020-06515.pdf

C. EPA Releases List of Disinfectants to Use Against COVID-19

Agency

Environmental Protection Agency (EPA)

Dates

Published Date: 03/05/2020

Summary

The Environmental Protection Agency has released a list of EPA-registered disinfectant products that are qualified for use against SARS-CoV-2, the novel coronavirus that causes COVID-19. The agency has used their Emerging Viral Pathogen program, which was developed in 2016, to determine which products will qualify to be effective. It is important for consumers to use the correct disinfectants. It is equally important to follow the directions for use on the product's master label, especially the contact time that the disinfectant should remain on the surface.

To view the list of EPA-registered disinfectant products please click this link:

https://www.epa.gov/sites/production/files/2020-03/documents/sars-cov-2-list_03-03-2020.pdf

Reference/Link

The link below will allow you to view EPA's website "List N: Disinfectants for use against SARS-SoV-2."

https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2

D. On-Site Civil Inspection Procedures

Agency

Environmental Protection Agency (EPA)

Dates

Published Date: 03/02/2020
Effective Date: 03/02/2020

Summary

This is a final rule by the Environmental Protection Agency (EPA) that fulfills the objectives outlined in the October 9, 2019 Executive Order (E.O.) 13892. This EO was made in order to increase transparency and fairness in Civil Administrative Enforcement and Adjudication. This rule describes Agency procedures for conducting on-site civil inspections.

This rule applies to on-site civil inspections conducted by federally credentialed EPA civil inspectors, federally credentialed contractors and Senior Environmental Employment (SEE) employees conducting inspections on behalf of EPA.

This Final Rule outlines ten elements of the inspections the agency carries out. This rule does not apply to investigations of environmental crimes.

1. *Timing of Inspections and Facility Notification*: When possible, for scheduled inspections EPA inspectors should take reasonable steps to work with the facility to agree on a workable schedule. EPA inspectors do have the authority to conduct inspections with or without prior notice to a facility.
2. *Inspector Qualifications*: EPA inspectors must hold a valid credential. EPA credentials are issued to inspectors that have completed training relevant to the statutory programs under which they will inspect and for the health and safety hazards they may encounter while conducting inspections.
3. *Obtaining Consent to Enter*: Upon arrival, EPA inspectors shall present their valid EPA Inspector Credentials to a facility employee, describe the authority and purpose of the inspection, and where possible seek the facilities' consent to enter. If a facility denies the inspector entry, the inspector may seek a warrant for entry.
4. *Opening Conference*: During an opening conference, the EPA inspector shall discuss the overall objectives of the inspection and announce they are a spokesperson for the EPA during the inspection.
5. *Physical Inspection*: EPA inspectors shall inspect the areas, units, sources and processes relevant to the scope of the inspection. The inspectors will document their observations with photos and/or notes.
6. *Managing Confidential Business Information (CBI)*: Inspectors shall complete appropriate, statute specific, CBI training before managing CBI. The EPA inspectors shall manage all CBI claims made by a facility during an inspection in accordance with 40 CFR part 2, subpart B.

7. *Interview Facility Personnel*: Interviews may include, but are not limited to, environmental contacts, process operators, contractors, maintenance personnel, process engineers, control room operators and other employees working in the area(s) of interest. The EPA inspector should document names and titles of all facility personnel interviewed including the places and dates in which these interviews occurred.
8. *Records Review*: EPA inspectors may request copies of many different types of records (paper, electronically scanned, downloaded or recorded through other digital storage devices), when appropriate, and record copies of records taken from the facility.
9. *Sampling*: EPA inspectors may take samples when appropriate. This inspector shall offer facility personnel to obtain split samples or to collect duplicate samples.
10. *Closing Conference*: EPA inspectors may discuss any outstanding questions, missing documents and areas of concern. EPA inspectors may also discuss next steps and how the facility will be contacted on the results of the inspection and identify the appropriate point of contact for further communication and coordination.

Following the inspection, EPA shall share an inspection report with the facility. This inspection report may be in the form of a checklist, letter, narrative, email message or other type of document.

Reference/Link

The link below will allow you to view/print this Final Rule.

https://www.govinfo.gov/content/pkg/FR-2020-03-02/pdf/2020-03508.pdf

E. National Pollutant Discharge Elimination System (NPDES) 2020 Issuance of the Multi-Sector General Permit for Stormwater Discharges Associated with Industrial Activity

Agency

Environmental Protection Agency (EPA)

Dates

Published Date: 03/02/2020
Comments Due: 05/01/2020

Summary

All of the Environmental Protection Agency's (EPA) Regions are requesting public comment on the 2020 National Pollutant Discharge Elimination System (NPDES) general permit for stormwater discharges associated with industrial activity. This may also be called the "2020 Multi-Sector General Permit" (MSGP) or the proposed permit. The existing MSGP will expire on June 4, 2020. The new permit will be issued for 5 years and will provide permit coverage to eligible operators in all areas of the country where the EPA is the NPDES permitting authority.

The proposed permit covers stormwater discharges from industrial facilities that are within 30 specific sectors. Some examples of these sectors are “Chemical and Allied Products Manufacturing,” “Oil and Gas Extraction," “Hazardous Waste Treatment Storage or Disposal," “Landfills and Land Application," “Scrap Recycling Facilities," “Land Transportation," and “Rubber, Miscellaneous Plastic Products, and Miscellaneous Manufacturing Industries.”

The permit is structured in nine parts. These parts are general requirements that apply to all facilities (e.g., eligibility requirements, effluent limitations, inspection and monitoring requirements, Stormwater Pollution Prevention Plan (SWPPP) requirements, and reporting and recordkeeping requirements) (Parts 1–7); industrial sector-specific conditions (Part 8); and state and Tribal-specific requirements applicable to facilities located within individual states or Indian Country (Part 9).

Additionally, there are appendices which provide proposed forms for the Notice of Intent (NOI), the Notice of Termination (NOT), the Conditional No Exposure Exclusion, the Discharge Monitoring Report (DMR), and the annual report, as well as step-by-step procedures for determining eligibility with respect to protecting historic properties and endangered species, and for calculating site-specific, hardness-dependent benchmarks.

In Section B. of the notice there is a summary of proposed permit changes.

1. The EPA proposes to streamline and simplify language throughout the permit to present the requirements in a more clear and readable manner.
2. The second changes are changes to the permit eligibility and authorization. To start, the eligibility for stormwater discharges to a federal CERCLA site will change. Additionally, the eligibility related to application of coal-tar sealcoat will change. Also, the discharge authorization related to enforcement action will have a wait time of 60 calendar days after NOI submission for any new discharges.
3. The third topic of proposed permit changes is to require operators to display public signage of permit coverage.
4. The fourth topic is consideration of major storm control measure enhancements. Under this fourth topic the EPA is proposing that operators would be required to consider implementing enhanced measures for facilities located in areas that could be impacted by stormwater discharges from major storm events that cause extreme flooding conditions.
5. The fifth topic is changes to monitoring procedures, including universal benchmark monitoring for all sectors, impaired waters monitoring, benchmark thresholds for selenium, arsenic, cadmium, magnesium, iron and copper, and sectors with new benchmarks.
6. The sixth topic is additional implementation measures (AIM). The proposed AIM requirements would replace corresponding sections regarding benchmark exceedances in the 2015 MSGP.
7. The final topic in Section B is revisions to sector-specific fact sheets. Please see the link at the end of this summary to find the sector-specific fact sheets.

In addition to the proposed changes described above the EPA is seeking comment on the following:

1. Eligibility related to use of cationic chemicals
2. The usefulness of a change to the NOI form
3. New acronym for the No Exposure Certification (NOE) to become NEC

4. Alternative approaches to benchmark monitoring
5. Inspection-only option in lieu of benchmark monitoring
6. Information about polycyclic aromatic hydrocarbons (PAHs)
7. Modifying the method for determining natural background pollutant contributions
8. Clarifications to Sector G monitoring requirements

The proposed permit, guidance documents and sector-specific fact sheet can be found at:

https://www.epa.gov/npdes/stormwater-discharges-industrial-activities

Reference/Link

The link below will allow you to view/print this notice.

https://www.govinfo.gov/content/pkg/FR-2020-03-02/pdf/2020-04254.pdf

F. Justice Department Ends Use of Environmental Settlements Tool

Agency

Department of Justice (DOJ)

Dates

Published Date: 03/12/2020

Summary

The Environmental Protection Agency, as well as other agencies, have entered into settlements that require defendants to expend funds to provide goods or services to third parties in lieu of the payment of penalties. This practice has been called Supplemental Environmental Projects (SEP). The EPA defines SEPs as "an environmentally beneficial project or activity that is not required by law, but that a defendant agrees to undertake as part of the settlement of an enforcement action."

The Assistant Attorney General, Jeffrey Bossert Clark, has found that this is in violation of the Miscellaneous Receipts Act, which requires any federal officer receiving funds on behalf of the United States to deposit them in the Treasury. In the past agencies have utilized SEPs on the rationale that SEPs do not trade penalties for projects because there is no penalty owed to the government until the settlement is finalized.

This has been a controversial topic for decades, the origin of SEPs dates back to about 1980. Moving forward Division attorneys negotiating consent decrees or compromise settlements in EPA cases should not include SEPs in those settlements.

Reference/Link

The link below will allow you to view/print this memorandum.

https://www.justice.gov/enrd/page/file/1257901/download

G. FMCSA Waiver For States, CDL Holders, CLP Holders, and Interstate Drivers Operating Commercial Motor Vehicles

Agency

Federal Motor Carrier Safety Administration (FMCSA)

Dates

Published Date: 03/24/2020

Summary

FMCSA has granted, until June 30, 2020, a waiver from certain regulations applicable to intrastate and interstate CDL and CDL permit holders and to other non-CDL interstate drivers operating commercial motor vehicles. COVID-19 outbreaks have led to widespread closures of State and Federal government offices, reduction of government and medical services, and disruption of transportation systems, including driver shortages and related interruption of supply chains, which are heavily dependent on continued CMV operations. FMCSA finds that the circumstances surrounding this waiver are unique because such government and medical operations are not providing their usual level of service.

This waiver extends the expiration date of CDL, CDL permits, driver licenses of non-CDL drivers operating commercial motor vehicles and medical cards until June 30, 2020 as long as they were not previously expired prior to March 1, 2020. CDL and CDLP holders are also provided relief from updating the State Driver Licensing Agency with a copy of their current medical certification. States are relieved from marking a driver as not medically certified due to an expired medical card and from downgrading a CDL or CDLP. Drivers operating under the waiver must carry a paper copy of their expired medical card.

This waiver does not alter any of the knowledge and skills testing requirements for obtaining either a CDL, CDL permit or a necessary endorsement. (examples: Veolia drivers who do not currently have a hazmat endorsement cannot transport hazardous materials that require placarding. Non-CDL drivers cannot operate a CMV that requires a CDL or CDLP.) It does not allow CDL or CDL permit holders to extend their licenses if they expired prior to March 1, 2020. It does not apply to a CDL or CDL permit holder if the driver's privileges have been suspended or withdrawn for traffic offenses. This waiver does not cover CDL, CDL permit holders or non-CDL drivers whose medical certification expired prior to March 1, 2020.

Drivers who cannot produce evidence of a prior medical certification that expired on or after March 1, 2020, are not covered under this waiver, including new drivers who have never obtained a medical certification.

Drivers who, since their last medical certificate was issued, have been diagnosed with a medical condition that would disqualify the driver from operating in interstate commerce, or who since their last medical certificate was issued, have developed a condition that requires an exemption or Skill Performance Evaluation from FMCSA are not covered under the waiver.

Veolia is also required to report any DOT accidents directly to the FMCSA within 5 days of the accident occurring.

Reference/Link

The link below will allow you to view/print this memorandum.

https://www.fmcsa.dot.gov/emergency/fmcsa-cdl-waiver-32420

H. CVSA Postpones International Roadcheck

Agency

Commercial Vehicle Safety Alliance (CVSA), Department of Transportation (DOT)

Dates

Published Date: 03/25/2020

Summary

International Roadcheck is a three-day enforcement initiative that highlights the importance of commercial motor vehicle safety through roadside inspections. Over that 72-hour period, commercial motor vehicle inspectors in jurisdictions throughout North America will conduct inspections on commercial motor vehicles and drivers. This year's focus will be on driver requirements. With last year's federal ELD full-compliance mandate in the US, the Alliance decided that this year's Roadcheck would be the perfect opportunity to revisit all aspects of roadside inspection driver requirements. This years International Roadcheck was scheduled to be May 5-7, 2020. Due to safety concerns revolving around COVID-19, CVSA announced that International Roadcheck 2020 has been postponed until later in the year.

CVSA has also stated that they will still be regularly inspecting trucks and added the following message:

"As we urgently respond to this time-sensitive crisis, we must remain diligent and committed to ensuring that the commercial motor vehicles and drivers providing essential goods and services to our communities are following motor carrier safety regulations," said CVSA president Sgt. John Samis, a state trooper in Delaware. "Safety doesn't take a break. It is always our top priority."

We will post in the Veolia Regulatory Update when CVSA establishes a new date. You can also stay up to date on the information by visiting the CVSA website for International Roadcheck:

https://www.cvsa.org/program/programs/international-roadcheck/

Reference/Link

The link below will allow you to view/print this announcement.

https://www.cvsa.org/news-entry/2020-roadcheck-postponed/

I. Registration and Reregistration Fees for Controlled Substance and List I Chemical Registrants

Agency

Drug Enforcement Agency (DEA)

Dates

Published Date: 03/12/2020
Comments Due: 05/15/2020

Summary

The Drug Enforcement Administration is proposing adjusting the fee schedule for registration and re-registration fees. The DEA believes this change is necessary to recover the costs of its Diversion Control Program. The Diversion Control Program (DCP) is responsible for maintaining a closed system of distribution by preventing the diversion of controlled substances and listed chemicals in the U.S. and enforcing the provisions of the Controlled Substances Act (CSA.) This program was established in part with the purpose of ending the deadly cycle of prescription opioid misuse.

The proposed amendments would codify new registration fees for business activities involving controlled substances, as well as list I chemicals and drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine. The proposed amendments would also codify existing practices of when DEA will issue refunds for application fees. The DEA has evaluated three fee structure options and chose the most reasonable option. A detailed analysis of the alternative options can be found under the section heading “Proposed Methodology for New Fee Calculation.”

The last fee increase was in 2012. Since 2012, the nature of the diversion control problem has increased in size and complexity. The following chart explains the proposed fee for each organization type:

Organization Type	Proposed Fee
Manufacturers of Controlled Substances	$3,699 per year
Distributors, Reverse Distributors, Importers and Exporters of Controlled Substances	$1,850 per year
Controlled Substance Business Activities Involving Dispensing (Pharmacy, Hospital/Clinic, Practitioner, Teaching Institution, Mid-level Practitioner)	$888 per 3 year cycle
All other business activities of controlled substances (Research, Narcotic Treatment Programs, and Chemical Analysis)	$296 per year
Manufacturers of List I Chemicals	$3,699 per year
Distributors, Importers, and Exporters of List I Chemicals	$1,850 per year

Reference/Link

The link below will allow you to view/print this memorandum.

https://www.govinfo.gov/content/pkg/FR-2020-03-16/pdf/2020-05159.pdf

J. Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List

&

Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review

Agency

Animal and Plant Health Inspection Service (APHIS), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

Dates

Published Date: 03/17/2020
Comments Dues: 05/18/2020

Summary

The Animal and Plant Health Inspection Service (APHIS) and the Centers for Disease Control and Prevention (CDC) are asking for public comments regarding the lists of biological agents, select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products. For the APHIS, this is done in accordance with the Agricultural Bioterrorism Protection Act of 2002. For the CDC, this is done in accordance with section 351a of the Public Health Service Act. Both of these acts require the biennial review of the list of select agents and toxins, and revisions as necessary.

The following select agent removals are being considered:

- Peronosclerospora philippinensis (Peronosclerospora sacchari)
- African horse sickness virus
- Bacillus anthracis (Pasteur strain)
- Brucella abortus
- Brucella melitensis
- Brucella suis
- Venezuelan equine encephalitis virus
- Botulinum Neurotoxin Producing Species of Clostridium
- Coxiella burnetii
- Rickettsia prowazekii
- Bacillus anthracis (Pasteur Strain)
- Short, Paralytic Alpha Conotoxins
- Diacetoxyscirpenol (DAS)
- Staphylococcal Enterotoxins

The following biological agents additions are being considered:

- New World Hantaviruses
- Old World Hantaviruses

The following exclusion limits are being considered:

- Saxitoxin based on the LD50 by ingestion is estimated as 0.3–1.0 mg/ person (Burrows et al., 1999) and estimated mortality rate of 15% for Paralytic Shellfish Poisoning (Rodrique, et al., 1990 and Hallegraeff, et al. 1995)
- Tetrodotoxin based on LD50 estimated 15–60 mg/kg by ingestion (Burrows et al., 1999); 2 mg/kg by inhalation; 8–14 mg/kg by injection (mouse, dog, rabbit) (Bane et al., 2014) and the recent puffer fish poisoning in 2008 Bangladesh involved 141 cases with 17 deaths (Islam et al., 2011)
- Botulinum neurotoxin estimated at 1 ug/kg by ingestion; 0.01–0.012 ug/kg by inhalation; 0.0013–0.0024 ug/kg by injection (Guzman et al., 2001)

Additionally, HHS/CDC is seeking public comment on whether Nipah virus should be identified as a Tier 1 select agent

Reference/Link

The links below will allow you to view/print these two advanced notices of proposed rulemaking.

https://www.govinfo.gov/content/pkg/FR-2020-03-17/pdf/2020-05499.pdf

&

https://www.govinfo.gov/content/pkg/FR-2020-03-17/pdf/2020-05477.pdf

K. Schedules of Controlled Substances: Placement of Cenobamate in Schedule V

Agency

Drug Enforcement Agency (DEA), Department of Justice

Dates

Published Date: 03/10/2020
Effective Date: 3/10/2020
Comments Due: 4/9/2020

Summary

On November 21, 2019, the U.S. Food and Drug Administration (FDA) approved a new drug application for XCOPRI (cenobamate) tablets. The Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place cenobamate in schedule V of the Controlled Substances Act (CSA).

This interim final rule became effective on March 10, 2020 but interested parties may file comments on or before April 9, 2020.

Schedule V substances have special requirements for handling. Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) cenobamate, or who desires to handle cenobamate, 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. Additionally, schedule V ubstances must be disposed of properly. There are also security, labeling and packaging, inventory, records and reports, prescriptions, manufacturing and distributing, importation and exportation and liability requirements for cenobamate and all schedule V substances.

Reference/Link

The link below will allow you to view/print this Interim Final Rule.

https://www.govinfo.gov/content/pkg/FR-2020-03-10/pdf/2020-04963.pdf