Veolia North America - Industrial Business Regulatory Update - April 2020

ENVIRONMENTAL UPDATES

A. ITRC; Per- and Polyfluoroalkyl Substances (PFAS) Technical and Regulatory Guidance Document; Guidance Document

TRANSPORTATION UPDATES

B. DOT/PHMSA; Options Related to Hazardous Materials Shipping Papers and Social Distancing during the COVID-19 Public Health Emergency; Notice

C. TSA; Exemption from Renewal of the Hazardous Materials Endorsement Security Threat Assessment for Certain Individuals; Notice of Temporary Exception

D. FMCSA; Controlled Substances and Alcohol Testing: State Driver's Licensing Agency Non-Issuance/Downgrade of Commercial Driver's License; Notice

E. DOT/FMCSA; Hours of Service Relief - FMCSA Emergency Declaration in Response To COVID-19; Emergency Declaration

HEALTH & SAFETY UPDATES

F. OSHA; Expanded Temporary Enforcement Guidance on Respiratory Protection Fit-Testing for N95 Filtering Facepieces in All Industries During the Coronavirus Disease 2019 (COVID-19) Pandemic; Memorandum

G. HHS; Approval Tests and Standards for Air-Purifying Particulate Respirators; Notice

H. Discretion in Enforcement when Considering an Employer's Good Faith Efforts During the Coronavirus Disease 2019 (COVID-19) Pandemic; Memorandum

MISCELLANEOUS UPDATES

I. Postal Service; New Mailing Standards for COVID-19 Related Category B Infectious Substances; Temporary Final Rule

J. DOJ/DEA; Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacturer of Fentanyl, as List I Chemicals, Final Rule

K. DOJ/DEA; Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I; Correction

L. DOJ/DEA; Schedules of Controlled Substances: Placement of Lemborexant in Schedule IV; Interim Final Rule

The information contained herein is provided by Veolia North America for general informational purposes only. This information should not be construed as legal advice or a legal opinion on any specific facts or circumstances. If you should have any questions, please contact Kevin McGrath, Director, Environment at kevin.mcgrath@veolia.com.

M. **DOJ/DEA; Control of Immediate Precursor Norfentanyl used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance; Final Rule**

A. Per- and Polyfluoroalkyl Substances (PFAS) Technical and Regulatory Guidance Document; Guidance Document

Agency

Interstate Technology Regulatory Council (ITRC)

Dates

Published Date: April 2020

Summary

The Interstate Technology Regulatory Council (ITRC) has created a guidance document to provide information on the current state of PFAS science and practice. This document was developed by a team of over 400 environmental practitioners drawn from state and federal government, academia, industry, environmental consulting and public interest groups.

An analysis of United States Environmental Protection Agency's (EPA's) Unregulated Contaminant Monitoring Rule (UCMR) program data has found that six million residents of the United States had drinking water with concentrations of perfluorooctanoic acid (PFOA) or perfluorooctane sulfonate (PFOS), or both, above the EPA's Lifetime Health Advisory (LHA) of 70 nanograms per liter (ng/L is equivalent to parts per trillion [ppt]) as of 2016. The primary focus of the PFAS regulation is to protect human health. PFAS regulation has been aimed at reducing the levels in public water systems.. Agencies have also used strategies to limit the use and release of PFAS. Unfortunately, little to no health-effects data are available for many PFAS.

The major federal and state statutes, regulations and policy initiatives that govern PFAS are described in the guidance document. The federal programs include the Toxic Substances Control Act (TSCA), the Safe Drinking Water Act (SDWA), and Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Several states have been involved in addressing PFAS contamination. States have utilized product labeling and consumer product laws to protect consumers from PFAS. In Washington, chemical action plans (CAPs) have been used to identify, characterize, and evaluate uses and releases of specific PBTs or metals. Some states, including Vermont and New York, have identified certain PFAs as a hazardous waste or a hazardous substance. Lastly, many states have implemented Drinking Water, Groundwater, Surface Water, Soil, and Remediation Programs. These states have either adopted the USEPA LHAs for PFOA and PFOS or selected the same health-based values, choosing to use the concentrations as advisory, non-regulated levels to guide the interpretation of PFOA and PFOS detections.

ITRC explained that in 2017 the New York State Department of Environmental Conservation (NYDEC) finalized regulations that identify PFOA, ammonium perfluorooctanoate, PFOS (the acid) and its salt, perfluorooctane sulfonate, as hazardous substances that may be found in Class B firefighting foams. This is specifically for Class B foams that contain at least 1% by volume of one or more of these four PFAS, and prohibit the release of one pound or more of each into the environment during use.

As a result of new developments occurring so frequently, the ITRC has created specific spreadsheets so the information can be updated and shared. Tables 4-1 and 4-2, provided as an Excel file, are intended to identify currently available U.S. and international standards and guidelines for groundwater, drinking water, surface water, and effluent or wastewater (Table 4-1), and soil (Table 4-2). Tables 5-1 and 5-2 summarize the differences in the PFOA (Table 5-1) and PFOS (Table 5-2) values for drinking water in the United States.

Some states have not yet developed values or adopted the USEPA LHA. For those states, it may be appropriate to consult with the lead regulatory authority (local or federal) to determine the appropriate values to use for site evaluation. The fact sheet user should visit the ITRC website (https://pfas-1.itrcweb.org/fact-sheets) to access current versions of the tables.

Reference/Link

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

https://pfas-1.itrcweb.org/fact_sheets_page/PFAS_Fact_Sheet_Regulations_April2020.pdf

B. Options Related to Hazardous Materials Shipping Papers and Social Distancing during the COVID-19 Public Health Emergency; Notice

Agency

Department of Transportation (DOT), Pipeline and Hazardous Materials Safety Administration (PHMSA)

Dates

Published Date: 04/10/2020

Summary

The U.S. Department of Transportation (DOT) Pipeline and Hazardous Materials Safety Administration (PHMSA) has created a notice in response to inquiries regarding the requirements of the Hazardous Materials Regulations (HMR; 49 CFR Parts 1 71-180) applicable to the exchange of shipping papers. Specifically, inquiries focused on the need to maintain social distancing between shippers and carriers.

The notice explains that under the HMR no physical contact between parties is required. The notice states an example of signing paperwork. In this example, they explain that shipping papers may be placed on a clipboard or on a table and the one party may step away while the paper is signed by the other party. The papers may also be sent via email or other means of electronic transmission to be signed. Additionally, a shipper may ask another person to sign on its behalf. This request may be made verbally, in writing, or electronically transmitted.

Reference/Link

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

https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2020-04/PHMSA%20Shipping%20Paper%20Notice.pdf

C. Exemption from Renewal of the Hazardous Materials Endorsement Security Threat Assessment for Certain Individuals; Notice of Temporary Exemption

Agency

Transportation Security Administration (TSA), United States Department of Homeland Security (DHS)

Dates

Published Date: 04/02/2020
Effective Date: 04/02/2020
Effective Until: 07/31/2020 unless modified by the TSA in a notice in the Federal Register

Summary

The Transportation Security Administration (TSA) has issued an exemption to address the issue of expiring hazardous materials (hazmat) endorsements and the requirement to undergo a security threat assessment conducted by TSA.

Currently, individuals wishing to transport hazardous materials via a commercial motor vehicle must undergo a security threat assessment (STA) conducted by TSA. The STA for a Hazardous Material Endorsement (HME) consists of criminal, immigration, and security threat checks. States are prohibited from issuing or renewing an HME unless the State first receives a determination that no security threat for the individual exists following a TSA conducted STA. An individual seeking renewal of an HME must initiate an STA at least 60 days before expiration of his/her current HME. The process of initiating an STA requires the individual to submit information either to the State driver licensing agency (SDLA) or a TSA enrollment center, including fingerprints and other required information at least 60 days before the expiration of the HME.

Due to the National Emergency concerning COVID-19, it may be impracticable for some commercial drivers to renew their STAs during this crisis therefore, TSA has determined that it is in the public interest to grant an exemption from the STAs for HMEs given the need for commercial drivers with an HME to continue working without interruption during this crisis.

State Exemption:

During the effective period of the exemption, a State may extend the expiration date of an eligible individuals' HME for a period of no more than 180 days without a new STA. The State must notify each eligible individual that he/she is subject to an STA for renewal of the HME and that he/she must initiate the STA at least 60 days before the extended expiration date of the HME. If it is not practicable for a State to give individualized notice to drivers, the State may publish general notice, for example, on the appropriate website. TSA will continue to recurrently vet these individuals against terrorism and other governmental watch lists and databases and reserves authority to direct a State to revoke an individual's HME immediately and at any time. For purposes of this exemption, an eligible individual is defined as an individual who held a valid, unexpired HME with an STA on or after March 1, 2020, which HME has expired or would otherwise expire between that date and the close of the effective period of this exemption.

This exemption does not apply to new HMEs nor does it affect any other requirements applicable to obtaining a commercial driver's license.

Reference/Link

The links below will allow you to view/print this notice of temporary exemption and see the posting in the federal register.

https://www.pmta.org/resources/Documents/TSANotice-COVID-19HME_TempExemption_9110-05-P.PDF

&

https://www.govinfo.gov/content/pkg/FR-2020-04-08/pdf/2020-07340.pdf

D. Controlled Substances and Alcohol Testing: State Driver's Licensing Agency Non-Issuance/Downgrade of Commercial Driver's License; Notice

Agency

Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT)

Dates

Published Date: 04/28/2020
Comments Due: 06/29/2020

Summary

FMCSA proposes to prohibit State Driver's Licensing Agencies (SDLAs) from issuing, renewing, upgrading, or transferring a commercial driver's license (CDL), or commercial learner's permit (CLP), for individuals prohibited under current regulations from driving a commercial motor vehicle (CMV) due to controlled substance (drug) and alcohol program violations. The CMV driving ban is intended to keep these drivers off the road until they comply with return-to-duty (RTD) requirements.

Reference/Link

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

https://www.govinfo.gov/content/pkg/FR-2020-04-28/pdf/2020-08230.pdf

E. Hours of Service Relief - FMCSA Emergency Declaration in Response To COVID-19; Emergency Declaration

Agency

Department of Transportation (DOT), Federal Motor Carrier Safety Administration (FMCSA)

Dates

Published Date: 03/13/2020
Effective Date: 03/13/2020
Effective Until: 05/15/2020 or Until the termination of the emergency, whichever occurs sooner

Summary

The Federal Motor Carrier Safety Administration (FMCSA) issued an Emergency Declaration providing an exemption from 49 CFR 390-399, Hours of Service (HOS) regulations for transportation in the support of emergency relief efforts related to the COVID-19 Pandemic. By execution of the Emergency Declaration, motor carriers and drivers providing direct assistance in support of relief efforts related to the COVID-19 outbreaks are granted emergency relief from Parts 390 through 399 of Title 49 Code of Federal Regulations, except as described in the declaration. The declaration defines "direct assistance" as transportation and other relief services provided by a motor carrier or its driver(s) incident to the immediate restoration of essential services, such as medical care, or essential supplies such as food, related to COVID-19 outbreaks during the emergency.

The declaration does not provide an exemption from the controlled substances and alcohol use and testing requirements (49 CFR Part 382), the commercial driver's license requirements (49 CFR Part 383), the financial responsibility (insurance) requirements (49 CFR Part 387), the hazardous material regulations (49 CFR Parts 100-180), applicable size and weight requirements or any other portion of the regulations not specifically exempted under 49 CFR § 390.23.

In accordance with 49 CFR § 390.23, the declaration was effective immediately and shall remain in effect until the termination of the emergency (as defined in 49 CFR § 390.5) or until 11 :59 P.M. (ET) on May 15, 2020, whichever occurs sooner.

Reference/Link

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

https://www.fmcsa.dot.gov/sites/fmcsa.dot.gov/files/2020-03/FMCSA%20Emergency%20Declaration%203.13.20.pdf

&

https://www.fmcsa.dot.gov/emergency/expanded-emergency-declaration-under-49-cfr-ss-39023-no-2020-002-relating-covid-19

F. Expanded Temporary Enforcement Guidance on Respiratory Protection Fit-Testing for N95 Filtering Facepieces in All Industries During the Coronavirus Disease 2019 (COVID-19) Pandemic; Memorandum

Agency

Occupational Safety and Health Administration (OSHA)

Dates

Published Date: 04/08/2020
Effective Until: To Be Announced by OSHA

Summary

The Occupational Safety and Health Administration (OSHA) has published a memorandum that expands the temporary enforcement guidance provided in OSHA's March 14, 2020 memorandum. This memorandum was for Compliance Safety and Health Officers for enforcing annual fit-testing requirements of the Respiratory Protection standard, 29 CFR § 1910.134(f)(2). This memorandum was in regard to supply shortages of N95s or other filtering facepiece respirators (FFRs) due to the coronavirus disease 2019 (COVID-19) pandemic. This memorandum now extends to all workplaces covered by OSHA where there is required use of respirators.

OSHA field offices will exercise enforcement discretion concerning the annual fit-testing requirement as long as employers have made good-faith efforts to comply with the requirements of the Respiratory Protection standard and to follow the steps outlined in the March 14, 2020 memorandum. Additionally, because supplies are scarce at this time, employers should assess engineering controls, work practices and administrative controls to identify if they can make changes to decrease the need for N95s or other filtering facepiece respirators (FFRs.)

Please check OSHA's webpage at www.osha.gov/coronavirus for updates.

Reference/Link

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

https://www.osha.gov/memos/2020-04-08/expanded-temporary-enforcement-guidance-respiratory-protection-fit-testing-n95

G. Approval Tests and Standards for Air-Purifying Particulate Respirators; Notice

Agency

Centers for Disease Control and Prevention, Health and Human Service (HHS)

Dates

Published Date: 04/14/2020
Comments Due: 08/12/2020

Summary

The Department of Health and Human Service (HHS) is publishing this interim final rule to update the regulatory requirements used by the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) to test and approve air purifying particulate respirators for use in the ongoing public health emergency. With this rulemaking, parallel performance standards are added to existing regulatory requirements for PAPRs to allow for the approval of respirators in a new class, PAPR100, that may be better suited to the needs of workers in the healthcare and public safety sectors. This rulemaking will have no substantive impact on the continued certification testing and approval by the NIOSH National Personal Protective Technology Laboratory of existing PAPR class HE (high-efficiency series) respirators or non-powered air-purifying particulate respirators, including N95 filtering facepiece respirators.

This rulemaking applies to air purifying particulate respirators and gas and vapor respirators which also incorporate a particulate filter. NIOSH is: (1) consolidating all air-purifying, particulate respirator requirements, whether powered or non-powered, into subpart K and (2) eliminating unneeded and archaic parts of the standard related to PAPRs better aligning PAPR particulate filter testing for a new class of PAPR with the requirements for non-powered particulate respirators. With this rulemaking, a new class of PAPR is established, PAPR100, in parallel with the current PAPR class HE.

Reference/Link

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

https://www.govinfo.gov/content/pkg/FR-2020-04-14/pdf/2020-07804.pdf

H. Discretion in Enforcement when Considering an Employer's Good Faith Efforts During the Coronavirus Disease 2019 (COVID-19) Pandemic; Memorandum

Agency

Occupational Safety & Health Administration (OSHA)

Dates

Published Date: 04/16/2020

Summary

Employers are faced with many difficult decisions during the Coronavirus Pandemic and one of these is protecting our employees from respiratory hazards and complying with the OSHA regulations. During this time the American College of Occupational and Environmental Medicine issued a recommendation that occupational spirometry testing and the Council for Accreditation in Occupational Hearing Conservation issued a recommendation that audiometric evaluations be suspended until normal operations have resumed. Both measures are ways to minimize the risk to healthcare workers and conserve personal protective equipment.

OSHA inspectors are to evaluate an employer's programs to see if they have made a good faith effort to comply with the standards. An example of good faith efforts is to schedule refresher training as soon as possible after the pandemic has settled down and a company can reasonably perform training safely. Additionally, Training can be performed online and should be documented for future agency inspections.Companies and also ensure the respirator and medical monitoring programs are reviewed, followed and meet the OSHA requirements set in the regulatory standards.

Other examples of good faith include: (1) Scheduling employees for their annual spirometry testing for clearance to wear a respirator when hospitals/clinics can safely perform the testing. (2) Performing some parts of the annual physicals by having a “virtual exam” completed where the employees complete required questionnaires and these are reviewed by the medical review officer to determine fitness for duty. The audiometric and spirometry testing parts of the exams would be performed as soon as possible once deemed safe to complete, to satisfy the requirements of the medical exam for the employee.

Employers and employees can comply with the OSHA regulations and make Good Faith Efforts so that OSHA inspections do not result in citations, but also show that every reasonable effort has been made to comply with the regulations. A working relationship with OSHA with open conversion and cooperation can assist with not receiving citations and fines during these Coronavirus pandemic times.

Reference/Link

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

https://www.osha.gov/memos/2020-04-16/discretion-enforcement-when-considering-employers-good-faith-efforts-during

I. New Mailing Standards for COVID-19 Related Category B Infectious Substances; Temporary Final Rule

Agency

Postal Service™

Dates

Published Date: 04/29/2020
Effective Date: 04/27/2020
Effective Until: until the Federal public health emergency is terminated

Summary

Due to the ongoing COVID-19 pandemic, the United States Postal Service is experiencing a greater demand for the transportation of Infectious Substances, Category B UN3373. Due to the infectious nature of these materials there is an increased need for higher levels of awareness, safety, and compliance. It is the responsibility of the shipper to ensure the packaging used to contain the infectious substances meet all the required standards.

The revisions to the Hazardous, Restricted and Perishable Mail regulations include replacing Publication 52, Hazardous, Restricted, and Perishable Mail, Appendix C, Packaging Instructions 6C, currently incorporated by reference, in order to support the rapid deployment of coronavirus (COVID–19) diagnostic tests using the mail during this public health emergency. In addition to the updated packaging instructions, all shippers of COVID–19 related Infectious Substances Category B UN3373 must obtain authorization from the Postal Service prior to mailing. 39 CFR 113.3 will be in place until the end of this public health emergency. The Postal Service will publish a notification upon termination in the federal register.

39 CFR 113.3 first explains in §113.3(a) that all shippers of COVID-19 related Infectious Substances Category B must obtain an authorization from the Postal Service prior to mailing. Only tests developed and being performed by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) or equivalent clinical oversight regulations as well as commercial tests and home collection kits authorized by the FDA or an Institutional Review Board will be considered for mailing. 39 CFR 113.3 (b) explains that the material must be triple-packaged, meeting the package requirements in 49 CFR 173.199. The outer packaging must be of adequate size to accommodate all required shipping information and markings. The size of the mark on each side must not be less than 50 mm (1.97 inches) in length, the width of the border lines at least 2 mm, and letter and numbers must be at least 6 mm (0.24 inches) high.

§113.3(c) describes the drop test in 49 CFR 178.609(d) and explains that the package must be capable of passing the drop test. §113.3(d) explains that shippers must provide clear instructions to users regarding the procedures to be followed for preparing the samples and the packaging materials. §113.3(e) describes the optional outer packaging. This includes a polybag covering, provided that the interior triple packaging is complete, the selvage edge of the wrapping is less than 2 inches, all required markings and address information are applied both on the interior rigid box and the additional outer polybag wrapping. §113.3(f) explains that only cold packs or dry ice may be used as a refrigerant and must be placed on the outside of the secondary packaging, if applicable. Lastly, §113.3(g) explains the "other allowance." This allowance is that only small quantities of Class 3, Class 8, Class 9 or other materials in Packing Groups II and III may be used to stabilize or prevent degradation of the sample, provided the quantity of such materials does not exceed 30 mL (1 ounce) or 30 g (1 ounce) in each inner package.

Reference/Link

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

https://www.govinfo.gov/content/pkg/FR-2020-04-29/pdf/2020-08256.pdf

J. Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacturer of Fentanyl, as List I Chemicals, Final Rule

Agency

Department of Justice (DOJ), Drug Enforcement Agency (DEA)

Dates

Published Date: 04/15/2020
Effective Date: 05/15/2020

Summary

The Drug Enforcement Agency (DEA) is finalizing the designation of N-(1-benzylpiperidin-4-yl)-N-phenylpropionamide (also known as *benzylfentanyl*), including its salts, and N-phenylpiperidin-4-amine (also known as *4-anilinopiperidine*; N Phenyl-4-piperidinamine; 4–AP), including its amides, its carbamates, and its salts, as list I chemicals under the Controlled Substances Act (CSA). The DEA made this proposition due to their use in clandestine laboratories to illicitly manufacture the schedule II controlled substance fentanyl.

This action subjects handlers of benzylfentanyl and 4-anilinopiperidine to the chemical regulatory provisions of the CSA and its implementing regulations. All transactions of benzylfentanyl or 4-anilinopiperidine or mixtures containing either of these chemicals are regulated, regardless of transaction size or quantity, and are subject to control under the CSA. As list I chemicals, imports and exports of benzylfentanyl and 4-anilinopiperidine will be regulated per 21 CFR part 1313.

The DEA has implemented an application process to exempt mixtures from the requirements of the CSA and its implementing regulations. The DEA may grant exemption status if the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance.

This final rule subjects any handlers of benzylfentanyl or 4-anilinopiperidine to all of the List I chemical regulations which pertain to the following:

1. Registration
2. Records and Reports
3. Importation and Exportation
4. Security
5. Administrative Inspection
6. Liability

Reference/Link

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

https://www.govinfo.gov/content/pkg/FR-2020-04-15/pdf/2020-07064.pdf

K. Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I; Correction

Agency

Department of Justice (DOJ), Drug Enforcement Agency (DEA)

Dates

Published Date: 04/10/2020
Effective Date: 04/10/2020
Effective Until: 05/06/2021

Summary

This posting in the Federal Register is a correction to the February 6, 2018 issue of the Federal Register. In that issue the Drug Enforcement Administration (DEA) published a temporary scheduling order placing fentanyl-related substances, as defined in the order, and their isomers, esters, ethers, salts and salts of isomers, esters, and ethers in schedule I of the Controlled Substances Act (CSA). That order was set to expire on February 6, 2020. However, the ''Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act,'' which became law on February 6, 2020, extended the temporary control of fentanyl-related substances until May 6, 2021. This correcting amendment reflects the new expiration date mandated by Congress. This correcting amendment is effective April 10, 2020 through May 6, 2021, and is applicable beginning February 6, 2018 until May 6, 2021. If the temporary scheduling of fentanyl related substances in schedule I of the CSA is made permanent, the DEA will publish a document in the Federal Register on or before May 6, 2021.

Reference/Link

The link below will allow you to view/print this Correction

https://www.govinfo.gov/content/pkg/FR-2020-04-10/pdf/2020-06984.pdf

L. Schedules of Controlled Substances: Placement of Lemborexant in Schedule IV; Interim Final Rule

Agency

Department of Justice (DOJ), Drug Enforcement Agency (DEA)

Dates

Published Date: 04/07/2020
Effective Date: 04/07/2020
Comments due:05/07/2020

Summary

On December 20, 2019, the U.S. Food and Drug Administration approved a new drug application for Dayvigo (lemborexant) tablets for oral use. Lemborexant is chemically known as (1R,2S)-2-[(2,4-dimethylpyrimidin-5-yl)oxymethyl]-2-(3-fluorophenyl)-N-(5-fluoropyridin-2-yl)cyclopropane-1-carboxamide. There has been a scheduling recommendation by the Department of Health and Human Services to schedule lemborexant in schedule IV of the Controlled Substances Act. The Drug Enforcement Agency (DEA) has issued an interim final rule to place lemborexant, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule IV of the CSA.

The DEA is seeking comments on this rulemaking. Comments must be submitted either electronically or in writing on or before May 7, 2020.

As a result of being placed in schedule IV of the CSA, Lemborexant is subject to the CSA's schedule IV regulatory controls. This pertains to the following:

1. Registration
2. Disposal of Stocks
3. Security
4. Labeling and Packaging
5. Inventory
6. Records and Reports
7. Prescriptions
8. Manufacturing and Distributing
9. Importation
10. Liability

Reference/Link

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

https://www.govinfo.gov/content/pkg/FR-2020-04-07/pdf/2020-07089.pdf

M. Control of Immediate Precursor Norfentanyl used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance; Final Rule

Agency

Department of Justice (DOJ), Drug Enforcement Agency (DEA)

Dates

Published Date: 04/17/2020
Effective Date: 05/18/2020

Summary

The Drug Enforcement Administration (DEA) is designating the precursor chemical, N-phenyl-N-(piperidin-4-yl)propionamide (norfentanyl) as an immediate precursor for the schedule II controlled substance fentanyl. This is a final rule that establishes the control of norfentanyl as a schedule II substance under the Controlled Substances Act (CSA).

This rulemaking becomes effective on May 18, 2020. The scheduling of norfentanyl as an immediate precursor of the schedule II controlled substance, fentanyl, subjects norfentanyl to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing and exporting of a schedule II controlled substance.

The regulatory requirements of schedule II substances under the Controlled Substances Act (CSA) pertain to the following:

1. Registration
2. Security
3. Labeling and Packaging
4. Quotas
5. Inventory
6. Records and Reports
7. Order Forms
8. Importation and Exportation
9. Administrative Inspection
10. Liability

Reference/Link

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

https://www.govinfo.gov/content/pkg/FR-2020-04-17/pdf/2020-07381.pdf