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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 157

[Docket No. RM81–19–000]

Natural Gas Pipelines; Project Cost and Annual Limits

AGENCY: Federal Energy Regulatory Commission, Energy.

ACTION: Final rule.

SUMMARY: Pursuant to the authority delegated by the Commission's regulations, the Director of the Office of Energy Projects (OEP) computes and publishes the project cost and annual limits for natural gas pipelines blanket construction certificates for each calendar year.

DATES: This final rule is effective March 3, 2021 and establishes cost limits applicable from January 1, 2021 through December 31, 2021.

FOR FURTHER INFORMATION CONTACT: Richard W. Foley, Chief, Certificates Branch 1, Division of Pipeline Certificates, (202) 502–8955.

SUPPLEMENTARY INFORMATION: Section 157.208(d) of the Commission's Regulations provides for project cost limits applicable to construction, acquisition, operation and miscellaneous rearrangement of facilities (Table I) authorized under the blanket certificate procedure (Order No. 234, 19 FERC ¶ 61,216). Section 157.215(a) specifies the calendar year dollar limit which may be expended on underground storage testing and development (Table II) authorized under the blanket certificate. Section 157.208(d) requires that the ''limits specified in Tables I and II shall be adjusted each calendar year to reflect the 'GDP implicit price deflator' published by the Department of Commerce for the previous calendar year.''

Pursuant to § 375.308(x)(1) of the Commission's Regulations, the authority for the publication of such cost limits, as adjusted for inflation, is delegated to the Director of the Office of Energy Projects. The cost limits for calendar year 2021, as published in Table I of § 157.208(d) and Table II of § 157.215(a), are hereby issued.

Effective Date

This final rule is effective March 3, 2021. The provisions of 5 U.S.C. 804 regarding Congressional review of final rules does not apply to the final rule because the rule concerns agency procedure and practice and will not substantially affect the rights or obligations of non-agency parties. The final rule merely updates amounts published in the Code of Federal Regulations to reflect the Department of Commerce's latest annual determination of the Gross Domestic Product (GDP) implicit price deflator, a mathematical updating required by the Commission's existing regulations.

List of Subjects in 18 CFR Part 157

Administrative practice and procedure, Natural gas, Reporting and recordkeeping requirements.

Issued: February 19, 2021.

Terry L. Turpin,

Director, Office of Energy Projects.

Accordingly, 18 CFR part 157 is amended as follows:

PART 157—APPLICATIONS FOR CERTIFICATES OF PUBLIC CONVENIENCE AND NECESSITY AND FOR ORDERS PERMITTING AND APPROVING ABANDONMENT UNDER SECTION 7 OF THE NATURAL GAS ACT

■ 1. The authority citation for part 157 continues to read as follows:

Authority: 15 U.S.C. 717–717w, 3301–3432; 42 U.S.C. 7101–7352.

■ 2. In § 157.208(d), Table I is amended by adding an entry for ''2021'' at the end of the table to read as follows:

§ 157.208 Construction, acquisition, operation, replacement, and miscellaneous rearrangement of facilities.

* * * * *

(d) * * *

TABLE I TO PART 157

Year	Limit	
	Auto. proj. cost limit (Col.1)	Prior notice proj. cost limit (Col.2)
* * * * *		
2021	$12,600,000	$35,600,000

* * * * *

■ 3. In § 157.215(a)(5), Table II is amended by adding an entry for ''2021'' at the end of the table to read as follows:

§ 157.215 Underground storage testing and development.

(a) * * *

(5) * * *

TABLE II TO PART 157

Year	Limit
* * * * *	
2021	$6,800,000

* * * * *

[FR Doc. 2021–04096 Filed 3–2–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–600]

Schedules of Controlled Substances: Placement of Lemborexant in Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule adopts, without change, an interim final rule with request for comments published in the **Federal Register** on April 7, 2020, placing lemborexant ((1*R*,2*S*)-2-[(2,4-dimethylpyrimidin-5-yl)oxymethyl]-2-(3-fluorophenyl)-*N*-(5-fluoropyridin-2-yl)cyclopropane-1-carboxamide), 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 Controlled Substances Act (CSA). With the issuance of this final rule, the Drug

Enforcement Administration maintains 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.

DATES: The effective date of this final rulemaking is March 3, 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, 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:

Background and Legal Authority

Under the Controlled Substances Act (CSA), as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (Pub. L. 114–89), when the Drug Enforcement Administration (DEA) receives notification from the Department of Health and Human Services (HHS) that the Secretary has approved a certain new drug and HHS recommends control in the CSA schedule II–V, DEA is required to issue an interim final rule, with opportunity for public comment and to request a hearing, controlling the drug within a specified 90-day timeframe and to subsequently issue a final rule. 21 U.S.C. 811(j). When controlling a drug pursuant to subsection (j), DEA must apply the scheduling criteria of 21 U.S.C. 811 (b) through (d) and 812(b). 21 U.S.C. 811(j)(3).

On April 7, 2020, DEA published an interim final rule to make lemborexant (including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible) a schedule IV controlled substance. 85 FR 19387. The interim final rule provided an opportunity for interested persons to submit comments as well as file a request for hearing or waiver of hearing, on or before May 7, 2020. DEA did not receive any requests for hearing or waiver of hearing.

Comments Received

DEA received five comments in response to the interim final rule for the placement of lemborexant into schedule IV of the CSA. The submissions were from individual or anonymous commenters. Two commenters provided support for the interim final rule, one commenter opposed the rule, one commenter solely included a link to potential malware, and one commenter expressed views on a subject not related to the rule. As these final two comments were outside the scope of this rulemaking, DEA did not summarize or respond to them below.

Support of the Interim Final Rule

A commenter supported controlling lemborexant as a schedule IV controlled substance, if such control helped to prevent abuse of, or the addiction to, this substance. Another commenter noted HHS, in its analysis, found that lemborexant had similar abuse potential to other schedule IV sedatives such as suvorexant and zolpidem, and therefore, agreed with HHS's recommendation of schedule IV control for lemborexant. In addition, this commenter referenced a study, conducted by Eisai, Inc. (the Sponsor of the new drug application for Dayvigo (lemborexant)), and recommended that DEA add this particular study analysis regarding abuse and dependency potential to DEA's final rule, under the ''Determination to Schedule Lemborexant'' section, to further support DEA's placing lemborexant in schedule IV.

DEA Response: DEA appreciates the support for this rulemaking. DEA determined in the interim final rule, and re-affirms in this final rule, that there is substantial evidence of a potential for abuse of lemborexant, and lemborexant warrants control in schedule IV. Regarding the commenter's request that DEA include the study analysis in this final rule, DEA assumes that the commenter is referring to the human abuse potential (HAP) study conducted by Eisai, Inc. In the event the commenter is referencing this study, DEA asserts that the HAP study conducted by the Sponsor was included in both the DEA and HHS lemborexant eight-factor reviews and in the interim final rule located in the ''Determination to Schedule Lemborexant'' section in Factor 2 and in the ''Determination of Appropriate Schedule'' in section 3 of the interim final rule.

Opposition to the Interim Final Rule

A commenter claimed that DEA did not rely on the pharmacological data for lemborexant or follow any of the other factors required to be considered under 21 U.S.C. 811(c) to determine the placement of lemborexant in schedule IV. Instead, the commenter stated that DEA relied on a ''small and unrepeated sample group'' and its subjective responses, which matched responses to the schedule IV sedative suvorexant. The commenter also contended that there is a disparity in DEA's scheduling treatment for lemborexant (schedule IV) and Rozarem (non-controlled), as these both are sedatives—with the same Food and Drug Administration (FDA)-approved indication—that exert pharmacological activity by other means than binding to gamma-aminobutyric acid (GABA) receptors. As such, the commenter considered DEA's decision to schedule lemborexant ''arbitrary and capricious.'' This commenter further stated that the placement of lemborexant in schedule IV of the CSA would increase the regulatory restrictions on a drug intended to treat insomnia, thereby causing many to resort to more dangerous and addictive substances such as benzodiazepines and other drugs that bind to the GABA receptor. Lastly, the commenter stated lemborexant is a new molecular entity thus evidence of actual abuse or potential for abuse liability does not exist. Therefore, the commenter asserted that DEA should either not place lemborexant in the same schedule as drugs with proven abuse potential, such as Xanax and Ambien, or delay scheduling lemborexant until evidence of actual abuse data can be produced using the eight-factors stipulated in 21 U.S.C. 811(c).

DEA Response: Regarding the commenter's point concerning the lack of appropriate pharmacological data in support of the abuse potential of lemborexant, DEA asserts that pharmacological data serves as only one portion of the data used to determine abuse potential and abuse liability. As stated in the interim final rule, while lemborexant is highly selective for both the orexin 1 and orexin 2 receptors and has little to no affinity to other central nervous system receptor sites associated with abuse potential, in a clinical HAP study of lemborexant, lemborexant produced statistically significant increases in positive subjective measures in the bipolar visual analog scale (*i.e.,* Drug Liking, Overall Drug Liking, Good Effects, High, Stoned, and Take Drug Again) that were greater than placebo and statistically similar to other sedatives in the same drug class. Thus, in this HAP study, lemborexant showed potential for abuse. Following comprehensive evaluation of all available data, including both preclinical and clinical data as related to the eight-factor analysis pursuant to 21 U.S.C. 811(c), HHS recommended schedule IV for lemborexant. Upon careful consideration of all available data, DEA concurred with HHS' recommendation that lemborexant possesses abuse potential comparable to other schedule IV depressants.

Regarding the commenter's concerns that the control of lemborexant as a schedule IV drug would negatively impact treatment choices and increase addiction risks, DEA contends that there

is no evidence to suggest that such control of lemborexant creates undue regulatory restrictions increasing the risk of addiction. Furthermore, a HAP study of lemborexant was conducted, the results of which indicate that lemborexant has an abuse potential that is greater than placebo and statistically similar to other controlled sedatives in schedule IV of the CSA. Therefore, DEA asserts that by adopting the interim final rule placing lemborexant in schedule IV of the CSA, there is no ''risk of restricting its prescribing'' and limiting treatment options for insomnia to ''more dangerous and addictive molecules.'' Rather, lemborexant is being placed in a schedule with other sedative/hypnotics that have similar abuse potential such as benzodiazepines, barbiturates, and muscle relaxants.

Regarding the commenter's point that lemborexant is a new molecular entity with unknown actual or potential for abuse, and the commenter's request for DEA to either not place lemborexant in schedule IV or to postpone such scheduling until there is evidence showing the requisite abuse potential, DEA's determination of the abuse liability of lemborexant in the interim final rule, and again in this final rule, is in agreement with that of HHS. In a clinical HAP study investigating the abuse potential of lemborexant, HHS concluded that lemborexant produced subjective responses that were similar to those for the schedule IV sedative suvorexant. In the context of drug development, HAP studies are conducted as a component of the safety evaluation of a new molecular entity. These studies are utilized by HHS, FDA, and the scientific community. They are accepted as repeatable and follow rigorous scientific guidelines. In effect, the HAP studies are indeed evidence showing the requisite abuse potential of lemborexant; therefore, no additional studies are necessary to prove potential for abuse. Additionally, HHS' evaluation of a HAP study conducted by the Sponsor concluded that lemborexant produces positive subjective effects and has abuse potential similar to that of schedule IV sedatives, such as suvorexant and zolpidem, which were used as positive controls in the study. DEA asserts that when the evidence of actual abuse is not available, both HHS and DEA rely upon data from preclinical and clinical studies to inform determinations on potential for abuse of a given substance. Therefore, upon evaluation of the above-mentioned clinical studies and other preclinical data, DEA concurred with HHS' findings that the abuse liability of lemborexant is similar to other substances placed in schedule IV (*i.e.,* benzodiazepines, barbiturates, and muscle relaxants) and therefore supported—and continues to support through this final rule—placement of lemborexant in schedule IV.

Finally, we address the commenter's claim that the control of lemborexant is improper because there is another substance, that is not controlled, which the commenter asserts has similar pharmacological properties to those of lemborexant. DEA contends that while both drugs are classified as sedatives with similar FDA-approved indications, they do not share the same pharmacological mechanism of action or abuse liability. Even assuming this assertion were correct, this is not a legal basis to decline to control a substance. The CSA does not require, as a condition of control under 21 U.S.C. 811, that every other substance with similar properties be simultaneously controlled.

Based on the rationale set forth in the interim final rule, DEA adopts the interim final rule without change.

Requirements for Handling Lemborexant

As indicated above, lemborexant has been a schedule IV controlled substance by virtue of the interim final rule issued by DEA in April 2020. Thus, this final rule does not alter the regulatory requirements applicable to handlers of lemborexant that have been in place since that date. Nonetheless, for informational purposes, we re-state here those requirements. Lemborexant 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, but not limited to, 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) lemborexant, or who desires to handle lemborexant, 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 intends to handle lemborexant, and is not registered with DEA, must submit an application for registration and may not handle lemborexant, unless DEA approves that application for registration, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person who obtains a schedule IV registration to handle lemborexant but who subsequently does not desire or is not able to maintain such registration must surrender all quantities of lemborexant, or may transfer all quantities of lemborexant to a person registered with DEA in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Lemborexant is subject to schedule III–V security requirements and must be handled and stored in accordance with 21 CFR 1301.71–1301.93. Non-practitioners handling lemborexant 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 lemborexant must comply with 21 U.S.C. 825 and 958(f), and be in accordance with 21 CFR part 1302.

5. *Inventory.* Every DEA registrant who possesses any quantity of lemborexant was required to keep an inventory of lemborexant on hand, as of April 7, 2020, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

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

7. *Prescriptions.* All prescriptions for lemborexant or products containing lemborexant 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 lemborexant may only be for the legitimate purposes consistent with the drug's labeling, or for research activities authorized by the Federal Food, Drug, and Cosmetic Act and the CSA.

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

10. *Liability.* Any activity involving lemborexant 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

This final rule, without change, affirms the amendment made by the interim final rule that is already in effect. Section 553 of the Administrative Procedure Act (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 and (2) HHS recommends control in CSA schedule II–V, DEA shall issue an interim final rule scheduling the drug within 90 days. Additionally, subsection (j) specifies that the rulemaking shall become immediately effective as an interim final rule without requiring DEA to demonstrate good cause. DEA issued an interim final rule on April 7, 2020, and solicited public comments on that rule. Subsection (j) further states that after giving interested persons the opportunity to comment and to request a hearing, the Attorney General, as delegated to the Administrator of DEA, shall issue a final rule in accordance with the scheduling criteria of 21 U.S.C. 811 (b) through (d) and 812(b). DEA is now responding to the comments submitted by the public and issuing the final rule in accordance with subsection (j).

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 final rule does not have federalism implications warranting the application of E.O. 13132. The final 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 final 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 was not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined and certifies 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 million 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 does 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 final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the U.S.-based companies to compete with foreign-based companies in domestic and export markets. However, pursuant to the CRA, DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ Accordingly, the interim final rule (85 FR 19387) amending 21 CFR part 1308, which published on April 7, 2020, is adopted as a final rule without change.

D. Christopher Evans,

Acting Administrator.

[FR Doc. 2021–04183 Filed 3–2–21; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 49

[EPA–R01–OAR–2020–0374; FRL–10018–74–Region 1]

Approval and Promulgation of Air Quality Implementation Plan; Mashantucket Pequot Tribal Nation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) approves the Mashantucket Pequot Tribal Nation's (MPTN or the Tribe) Tribal Implementation Plan (TIP) under the Clean Air Act (CAA) to regulate air pollution within the exterior boundaries of the Tribe's reservation. The TIP is one of two CAA regulatory programs that comprise the Tribe's Clean Air Program (CAP). EPA approved the Tribe for treatment in the same manner as a State (Treatment as State or TAS) for purposes of administering New Source Review (NSR) and Title V operating permits under the CAA on July 10, 2008. In this action we act only on those portions of MPTN's CAP that constitute a TIP containing severable elements of