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: Interim final rule with request for comments.

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 (1*R*,2*S*)-2-[(2,4-dimethylpyrimidin-5-yl)oxymethyl]-2-(3-fluorophenyl)-*N*-(5-fluoropyridin-2-yl)cyclopropane-1-carboxamide. The Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place lemborexant 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 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 rulemaking is April 7, 2020. 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). Electronic comments must be submitted, and written comments must be postmarked, on or before May 7, 2020. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons may file a request for hearing or waiver of hearing in accordance with

21 U.S.C. 811(j)(3) and 21 CFR 1308.44. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing, together with a written statement of position on the matters of fact and law asserted in the hearing, must be received on or before May 7, 2020.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–600'' 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 the site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that 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 the electronic submission 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 regarding his position on the matter of fact and law involved in such hearing, must be sent to: Drug Enforcement Administration. Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ. 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: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) 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 it to be made 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 it to be made 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.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. 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 directed above as confidential.

An electronic copy of this document and supplemental information, including the complete Department of Health and Human Services (HHS) and DEA eight-factor analyses, to this interim final rule 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 include a statement of interest 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 a hearing 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 Improving Regulatory Transparency for New Medical Therapies Act, Public Law 114–89, 2(b), 129 tat. 700 (2015), 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 HHS has advised DEA that a New Drug Application (NDA) has been submitted for a drug that has a stimulant, depressant, or hallucinogenic effect on the central nervous system (CNS), and that it appears that such drug has an abuse potential; and (2) the Secretary of HHS recommends that DEA control the drug in schedule II, III, IV, or V pursuant to 21 U.S.C. 811(a) and (b). In these circumstances. DEA is required to issue an interim final rule controlling the drug within 90 days.

The law further states that the 90-day timeframe starts the later of: (1) The date DEA receives HHS' scientific and medical evaluation and scheduling recommendation, or (2) the date DEA receives notice of the NDA approval by HHS. In addition, the law specifies that the rulemaking shall become immediately effective as an interim final rule without requiring DEA to demonstrate good cause therefore. Thus, the purpose of subsection (j) is to speed the process by which DEA schedules newly approved drugs that are currently either in schedule I or not controlled (but which have sufficient abuse potential to warrant control) so that such drugs may be marketed without undue delay following FDA approval.[1]

Subsection (j) further provides that the interim final rule 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 subsections 21 U.S.C. 811(b), (c), and (d) and 21 U.S.C. 812(b).

Lemborexant [(1*R*,2*S*)-2-[(2,4-dimethylpyrimidin-5-yl)oxymethyl]-2-(3-fluorophenyl)-*N*-(5-fluoropyridin-2-yl)cyclopropane-1-carboxamide] is a new molecular entity with CNS depressant properties. Lemborexant acts as an antagonist at both orexin-1 and orexin-2 receptors (OX1R and OX2R, respectively). On December 27, 2018, Eisai, Inc., submitted an NDA for Dayvigo (lemborexant), 5 and 10 mg oral tablets, with the proposed dosage suggestion of 5 mg, not to exceed a maximum dose of 10 mg once a day. On March 9, 2020, DEA received a letter from FDA, dated March 5, 2020, notifying DEA that FDA, on December 20, 2019, approved the NDA for Dayvigo (lemborexant), under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.[2] Lemborexant has not been marketed in any other country for any medical indication.

Determination To Schedule Lemborexant

On January 9, 2020, DEA received from HHS a scientific and medical evaluation (dated December 19, 2019) entitled ''Basis for the Recommendation to Control Lemborexant 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 lemborexant, along with HHS's recommendation to control lemborexant 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 lemborexant 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's recommendation, the NDA approval by HHS/FDA, and DEA's determination, DEA is issuing this interim final rule to schedule lemborexant 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–600.'' 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

As noted by HHS, lemborexant is a new molecular entity that has not been marketed in the United States or any other country. Thus, evidence regarding its diversion, illicit manufacture, or deliberate ingestion is currently lacking. DEA notes that there are no reports for lemborexant in the National Forensic Laboratory Information System (NFLIS),[3] which collects drug identification results from drug cases submitted to and analyzed by state and local forensic laboratories. There were also no reports in STARLiMS,[4] DEA's laboratory drug evidence data system of record.

As stated by HHS, lemborexant is a sedative that is highly selective for both the OX1R and OX2R receptors and has little to no affinity to other CNS receptor sites associated with abuse potential. In a clinical 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.

[1] Given the parameter 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.

[2] *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/212028Orig1s000ltr.pdf,* accessed March 11, 2020.

[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. NFLIS data were queried January 15, 2020.

[4] On October 1, 2014, DEA implemented STARLiMS (a web-based, commercial laboratory information management system) to replace the System to Retrieve Information from Drug Evidence (STRIDE) as its laboratory drug evidence data system of record. DEA laboratory data submitted after September 30, 2014, are reposited in STARLiMS. STARLiMS data were queried January 15, 2020.

2. Scientific Evidence of Its Pharmacological Effects, if Known

According to HHS, lemborexant primarily acts as a dual orexin receptor antagonist and does not bind with any other CNS receptors that are typically associated with abuse, such as opioid or cannabinoid receptors, GABAergic, and other ion channels. According to HHS, general behavioral studies in animals indicate that acute oral administration of lemborexant using supratherapeutic doses (100, 300, and 1000 mg/kg), produced no overt behavioral changes in hindlimb foot splay, forelimb grip strength, hindlimb grip strength, and rectal temperature in cage-side, hand-held, and open-field using functional observational methods. Additionally, lemborexant, even at supratherapeutic doses, does not significantly impair motor coordination. In drug discrimination studies, which are used to predict subjective effects in humans, lemborexant and suvorexant (a schedule IV substance which is another known dual orexin receptor antagonist) did not fully mimic stimulus effects of zolpidem, a schedule IV sedative. In a self-administration study in rhesus monkeys, the rewarding effects of lemborexant were insufficient to produce reinforcement.

According to HHS, in a human abuse potential (HAP) study conducted by the Sponsor, lemborexant (at therapeutic and supratherapeutic doses) produced statistically significant increases on positive subjective measures in the bipolar visual analog scale (VAS) (*i.e.,* Drug Liking, Overall Drug Liking, Good Effects, High, Stoned, and Take Drug Again) that were greater than placebo and statistically similar to suvorexant and/or zolpidem (schedule IV substances). With respect to two subjective measures, such as drowsiness and sedation, lemborexant, similar to zolpidem and suvorexant, produced statistically significantly greater scores than placebo. HHS concluded that lemborexant produces positive subjective effects and has an abuse potential similar to that of schedule IV sedatives, such as suvorexant and zolpidem, which were used as positive controls in the aforementioned study. According to HHS, in multiple-dose Phase I studies, lemborexant produced dose-dependent ''abnormal dreams.'' There were few incidents of abuse-related adverse events (AEs), such as ''euphoric mood,'' ''disturbance in attention,'' and ''memory impairment.'' Furthermore, in Phase 2 clinical studies, lemborexant produced dose dependent somnolence. This response was considered appropriate given the proposed therapeutic use for lemborexant as a treatment for insomnia. No additional abuse-related AEs were reported by participants at an incidence greater than 1.0 percent. As per the adverse event data obtained from Phase 1 and Phase 2/3 clinical safety and efficacy trials, there were no significant abuse-related signals.

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

Lemborexant is a new molecular entity, chemically known as (1*R*,2*S*)-2-[(2,4-dimethylpyrimidin-5-yl)oxymethyl]-2-(3-fluorophenyl)-*N*-(5-fluoropyridin-2-yl)cyclopropane-1-carboxamide. It is nearly insoluble in water and heptane; ''sparingly'' soluble in 1-octanol; very soluble in dimethyl sulfoxide; and freely soluble in methanol, acetone, ethyl acetate, and benzyl alcohol. Additionally, lemborexant is soluble in acetonitrile and ethanol. On December 20, 2019, FDA approved an NDA for lemborexant for medical use for the treatment of insomnia in adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance. Thus, lemborexant has an accepted medical use in the United States. Lemborexant will be marketed as a once daily tablet taken before bedtime, with at least 7 hours remaining before the planned time of awakening. The recommended dose for lemborexant is 5 mg; however, the dosage may be increased to 10 mg based on clinical response and tolerability.[5]

4. Its History and Current Pattern of Abuse

There is no information available relating to the history and current pattern of abuse of lemborexant because this drug is not currently marketed in any country. As stated in Factor 1, DEA notes that there has been no diversion of lemborexant based on NFLIS and STARLiMS data. HHS notes that lemborexant produces abuse-related signals and abuse potential similar to that of the schedule IV controlled substance suvorexant.

5. The Scope, Duration, and Significance of Abuse

Lemborexant as a single active ingredient in a drug product is currently not marketed in any country. Thus, information on the scope, duration, and significance of abuse for lemborexant is lacking. As described in Factor 4, NFLIS and STARLiMS databases have no evidence of law enforcement encounters of lemborexant. However, as HHS notes, data from preclinical and clinical studies summarized in Factor 2 indicate that the scope, duration, and significance of abuse for lemborexant would be similar to those of suvorexant, a schedule IV substance. As stated by HHS, data from animal and human studies indicate that lemborexant has an abuse potential similar to that of suvorexant.

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

As stated by HHS, the public health risk associated with lemborexant is largely a risk to the individual due to its abuse potential. The extent of abuse potential of a drug is an indication of its public health risk. Data from the preclinical and clinical studies suggest that the abuse potential of lemborexant is similar to schedule IV substances, such as suvorexant and zolpidem. Lemborexant, similar to schedule IV sedatives, is likely to pose a public health risk of abuse upon marketing in the United States.

7. Its Psychic or Physiological Dependence Liability

Physical dependence for lemborexant was tested in a rat physical dependence study and during Phase 2/3 clinical trials. Based on the data from these studies, HHS concluded that lemborexant lacked physical dependence potential. According to HHS, in the HAP study (presented in Factor 2), lemborexant administration was associated with positive subjective effects as assessed by participant responses to measures of Drug Liking, Overall Drug Liking, Good Drug Effects, High, Stoned, and Take Drug Again. The results indicated that the responses for lemborexant were similar to that of positive control drugs, such as zolpidem and suvorexant. Thus, it is likely that lemborexant can produce psychic dependence similar to that of schedule IV drugs, such as zolpidem and suvorexant.

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

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

Conclusion

After considering the scientific and medical evaluation conducted by HHS, HHS's recommendation, and its own eight-factor analysis, DEA has determined that these facts and all

[5] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/212028s000lbl.pdf,* accessed February 6, 2020.

relevant data constitute substantial evidence of a potential for abuse of lemborexant. As such, DEA hereby schedules lemborexant 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 Acting Administrator of DEA, pursuant to 21 U.S.C. 812(b)(4), finds that:

1. Lemborexant has a low potential for abuse relative to the drugs or other substances in schedule III.

Lemborexant is a dual orexin receptor antagonist, which produces sedation in human behavioral studies. In the HAP study, therapeutic and supratherapeutic doses of lemborexant produced positive subjective responses such as Drug Liking, Overall Drug Liking, Good Drug Effects, High, Stoned, and Take Drug Again that were statistically significantly greater than those produced by placebo. These responses of lemborexant are similar to those produced by schedule IV drugs suvorexant and zolpidem. Because lemborexant is similar to zolpidem and suvorexant in its abuse potential, lemborexant has a low potential for abuse relative to the drugs and other listed substances in schedule III of the CSA.

2. Lemborexant has a currently accepted medical use in the United States.

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

3. Lemborexant may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

As stated by HHS, data from a rat physical dependence study, as well as a physical dependence assessment at the conclusion of the Phase 2/3 clinical trials, showed that lemborexant did not produce withdrawal symptoms indicative of physical dependence. In the HAP study, lemborexant produced positive subjective responses to measures such as Drug Liking, Overall Drug Liking, Good Drug Effects, High, Stoned, and Take Drug Again that were greater than placebo and similar to that of the schedule IV drugs zolpidem and suvorexant. This data suggests that lemborexant can produce psychic dependence to a similar extent as zolpidem and suvorexant. Thus, abuse of lemborexant may lead to limited psychological dependence relative to the drugs or other substances in schedule III of the CSA.

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

Requirements for Handling Lemborexant

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 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 currently handles or intends to handle lemborexant and is not registered with DEA must submit an application for registration and may not continue to handle lemborexant, 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.

2. *Disposal of stocks.* Any person who does not desire or is not able to maintain a schedule IV registration must surrender all quantities of currently held lemborexant or may transfer all quantities of lemborexant to a person registered with DEA in accordance with 21 CFR part 1317, in additional 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 1301.71–1301.77. Non-practitioners handling lemborexant must also comply with the employee screening requirements of 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(e), and be in accordance with 21 CFR part 1302.

5. *Inventory.* Every DEA registrant who possesses any quantity of lemborexant must take an inventory of lemborexant on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who becomes registered with DEA to handle lemborexant must take an initial inventory of all stocks of controlled substances (including lemborexant) 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.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including lemborexant) on hand at least 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.

6. *Records and Reports.* DEA registrants must maintain records and submit reports for lemborexant, 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 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 FDCA 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

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 interim final rule 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, the law specifies that the rulemaking shall become immediately effective as an interim final rule without requiring DEA to demonstrate good cause.

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

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 12866 and the principles reaffirmed in Executive Order 13563.

This interim final rule is not an Executive Order 13771 regulatory action pursuant to Executive Order 12866 and OMB guidance.[6]

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 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 Executive Order 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 Executive Order 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. Under 21 U.S.C. 811(j), DEA is not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply to this interim final rule.

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. 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 United States-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 interim final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, 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. Amend § 1308.14 by:
■ a. Redesignating paragraphs (c)(30) through (c)(56) as (c)(31) through (c)(57); and
■ b. Adding new paragraph (c)(30).
The addition reads as follows:

§ 1308.14 Schedule IV.

* * * * *

(c) * * *

(30) Lemborexant	2245

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Uttam Dhillon,

Acting Administrator.

[FR Doc. 2020–07089 Filed 4–6–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 56 and 57

[Docket No. MSHA–2019–0007]

RIN 1219–AB88

Electronic Detonators

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Mine Safety and Health Administration (MSHA) confirms the effective date for the direct final rule, Electronic Detonators, which was published on January 14, 2020, to revise certain safety standards for explosives at metal and nonmetal mines.

DATES: The effective date of the final rule published in the **Federal Register**

[6] Office of Mgmt. & Budget, Exec. Office of The President, Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017 Titled ''Reducing Regulation and Controlling Regulatory Costs'' (Feb. 2, 2017).