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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-558]

Schedules of Controlled Substances: Placement of Lasmiditan in Schedule V

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule with request for comments.

SUMMARY: On October 11, 2019, the U.S. Food and Drug Administration approved a new drug application for Reyvow (lasmiditan) tablets for oral use. Lasmiditan is chemically known as [2,4,6-trifluoro-*N*-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide]. Thereafter, the Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place lasmiditan in schedule V of the Controlled Substances Act (CSA). In accordance with the CSA, as revised by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing lasmiditan, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule V of the CSA.

DATES: The effective date of this rulemaking is [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. 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 [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

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 must be received on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-558" on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. 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/DRW, 8701 Morrissette Drive, Springfield, VA 22152.

- *Hearing requests:* All requests for hearing and waivers of participation 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/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, VA 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 (FOIA) 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 and Drug Enforcement Administration eight-factor analyses, to this interim final rule are available at *http://www.regulations.gov* for easy reference.

Request for Hearing, or Waiver of Participation in Hearing

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. 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 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 (Pub. L. 114–89), which was signed into law on November 25, 2015, the DEA is required to commence an expedited scheduling action with respect to certain new drugs approved by the U.S. Food and Drug Administration (FDA). As provided in 21 U.S.C. 811(j), this expedited scheduling is required where both of the following conditions apply: (1) The Secretary of the Department of Health and Human Services (Secretary of HHS or the Secretary) 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 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 the HHS scientific and medical evaluation/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 therefor. 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).

Lasmiditan [2,4,6-trifluoro-*N*-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide] is a new molecular entity with central nervous system (CNS) depressant properties. Lasmiditan is a 5-hydroxytryptamine (5-HT, serotonin) 1F receptor agonist. One of its metabolites has low $GABA_A$ channel positive allosteric activity. On October 11, 2018, Eli Lilly and Company (Sponsor) submitted an NDA to FDA for Reyvow (lasmiditan) 50 and 100 mg oral tablets. On November 4, 2019, DEA received notification that FDA, on October 11, 2019, approved the NDA for Reyvow (lasmiditan),

[1] Given the parameters of subsection (j), in DEA's view, it would not apply to a reformulation of a drug containing a substance currently in schedules II through V for which an NDA has recently been approved.

under section 505(c) of the FDCA, for the acute treatment of migraine with or without aura in adults.[2]

Determination to Schedule Lasmiditan.

On November 4, 2019, DEA received from HHS a scientific and medical evaluation document (dated October 23, 2019) prepared by the FDA related to lasmiditan. This document contained an eight-factor analysis of the abuse potential of lasmiditan, along with HHS' recommendation to control lasmiditan under schedule V of the CSA.

On December 4, 2019, the DEA requested clarification from HHS regarding supporting evidence for factors 6 and 7 listed in 21 U.S.C. 811(c), as well as the third finding under 21 U.S.C. 812(b)(5), for placement of lasmiditan in schedule V. HHS responded to the DEA via a letter on January 15, 2020, with the necessary clarification.

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 document pursuant to 21 U.S.C. 811(c). DEA concluded that lasmiditan met the 21 U.S.C. 812(b)(5) criteria for placement in schedule V of the CSA.

Pursuant to subsection 811(j), and based on the HHS recommendation, NDA approval by HHS/FDA, and DEA's determination, DEA is issuing this interim final rule to schedule lasmiditan as a schedule V 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 the 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

[2] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/211280Orig1s000ltr.pdf

"DEA-558." 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, lasmiditan is a new molecular entity that has not been marketed in the United States or any other country. As a result, information on the actual abuse of lasmiditan is limited. According to HHS, lasmiditan is not currently available for medical treatment, lasmiditan has not been diverted from legitimate sources, and individuals have not taken the substance in amounts sufficient to create a hazard to public health and safety. DEA further notes that there are no reports for lasmiditan 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.

Data from HHS outlined in Factors 2 and 3 demonstrate that lasmiditan is a 5-hydroxytryyptamine-1F (5-HT_{1F}) receptor agonist. There are no 5-HT_{1F} receptor agonists currently controlled in the CSA. Lasmiditan at the highest dose tested did produce reinforcing effects in a rat self-administration assay. Drug-liking visual analog scale (VAS) for lasmiditan were significantly higher than placebo and significantly lower than the schedule IV benzodiazepine alprazolam in an abuse potential study in humans (see Factor 3).

[3] NFLIS is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by State and local forensic laboratories in the United States. NFLIS data were queried on 11/14/2019.

[4] STARLiMS is a laboratory information management system that systematically collects results from drug chemistry analyses conducted by the DEA laboratories. On October 1, 2014, STARLiMS replaced STRIDE as the DEA laboratory drug evidence data system of record. STARLiMS data were queried on 11/18/2019.

2. *Scientific Evidence of Its Pharmacological Effects, if Known:* According to HHS, lasmiditan functions as a 5-HT_{1F} receptor agonist. HHS also further stated that lasmiditan does not bind to various other receptor targets (opioid, cannabinoid, GABAergic, or other ion channels) that are typically associated with abuse.

As shown by the studies summarized by HHS, lasmiditan did not produce abuse-related behaviors in the toxicity studies within mice, rats, and dogs. HHS stated that the studies demonstrating depressant effects such as weight loss, sedation, and hypothermia produced by lasmiditan could be due to its toxic concentrations of lasmiditan. In addition, results of the drug discrimination assay demonstrated that lasmiditan did not generalize to the discriminative stimulus effects of the benzodiazepine lorazepam (schedule IV); however, lasmiditan did produce reinforcing effects in the self-administration assay.

HHS described results from a Phase 1, randomized, double-blind, placebo-and active-controlled, crossover clinical trial in adult subjects who were recreational poly-drug users. The primary objective of this study was to assess the abuse potential of lasmiditan compared to alprazolam and placebo using the maximal effect score (E_{max}) of the at-the-moment 100-mm bipolar Drug Liking VAS.

Lasmiditan was evaluated by the comparison of Drug Liking E_{max} between each dose of lasmiditan and placebo. All doses of lasmiditan (100 mg, 200 mg, and 400 mg) produced significantly higher E_{max} than that of placebo indicating that lasmiditan has abuse potential. However, these effects of all doses of lasmiditan were significantly lower than alprazolam on mean E_{max} of Drug Liking.

Lasmiditan 200 mg (therapeutic dose), lasmiditan 400 mg (supratherapeutic dose), and alprazolam 2 mg (43-49 percent) produced euphoric mood to a similar extent. The lower dose of lasmiditan (100 mg) produced euphoric moods in 25 percent of subjects. Alprazolam produced a feeling of relaxation in more subjects than that produced by any dose of lasmiditan. According to HHS, this pattern of adverse events (AEs) suggests that lasmiditan has a similar or slightly less potential for abuse than alprazolam.

According to HHS, the Sponsor conducted eighteen Phase 1 studies in which AEs, including abuse-related AEs, were evaluated. In Phase 1, single-dose studies with healthy subjects, lasmiditan produced somnolence, feeling drunk, and euphoric mood. Euphoric mood occurred in five out of twelve studies for lasmiditan, and one out of seven studies for a control group. According to HHS, overall, the data from Phase 1 studies indicated that lasmiditan had more abuse-related AEs than placebo, and alprazolam showed a greater incidence of abuse-related AEs as compared to lasmiditan in one study.

HHS reviewed data from five Phase 2 and 3 studies and stated that, at therapeutic doses, lasmiditan displays abuse-related AEs to a greater extent than placebo. However, these AEs occur at a low frequency (about one percent).

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* Appearing as a white to off-white solid, lasmiditan is highly soluble in water and freely soluble in methanol. Per HHS, none of the steps in the manufacturing process of lasmiditan produces or utilizes substances that have a known potential for abuse, nor can they be easily modified to generate a substance with abuse potential. A high level of expertise in and knowledge of organic chemistry is required to synthesize lasmiditan.

Rat studies demonstrate that lasmiditan has a half-life of approximately 31 hours. HHS also described lasmiditan pharmacokinetic data from another study conducted in beagle dogs in the fasted (overnight) state versus the fed state. The time measurement for maximal concentration (T_{max}) was the only parameter that significantly differed between the fed (3.5 hours) and the fasted (1.25 hours) state, indicating that food has a significant slowing effect on the oral absorption of lasmiditan.

A separate study in male rats was conducted to compare the plasma and brain pharmacokinetic parameters, in addition to evaluating the bioavailability of lasmiditan. Results indicate that lasmiditan crosses the blood brain barrier and collects in the brain, producing exposure levels 2.5- to 3-fold higher than those in plasma. The T_{max} in both plasma and brain was reached in 30 minutes. However, the maximum serum concentration was two- and three-fold higher in the brain as compared to plasma levels following oral and IV administration, respectively. The oral bioavailability of the drug was 63.3 percent.

As described by HHS, an in-vitro study was conducted to identify the human cytochrome P450 isozymes responsible for the in-vitro metabolism of lasmiditan. Results indicated the possible involvement of CYP1A2 in the production of metabolites M7, M8, and M18; CYP2D6 and CYP2C9 in the production of M7 and M18; and CYP2C19 and CYP3A4 in the production of M7 and M18.

4. *Its History and Current Pattern of Abuse:* Lasmiditan was approved by FDA on October 11, 2019. According to HHS, as a single active ingredient in a drug product formulation, lasmiditan has not been approved for therapeutic use in any other country. There is no information available relating to the history and current pattern of abuse of

this formulation of lasmiditan or the active ingredient. As stated in Factor 1, DEA notes that there has been no diversion of lasmiditan based on NFLIS and STARLiMS data.

5. *The Scope, Duration, and Significance of Abuse:* As described in Factor 4, lasmiditan as a single entity has not been approved for therapeutic use outside of the United States. A search by DEA of the NFLIS and STARLiMS databases found no evidence of law enforcement encounters of lasmiditan in the United States. Based on the preclinical and clinical study data described by HHS (see Factor 2, above), and on available epidemiological data, the scope, duration, and significance of lasmiditan abuse would likely be lower than substances in schedule IV of the CSA and similar to that of a drug controlled in schedule V.

6. *What, if Any, Risk There Is to the Public Health:* As stated by HHS, the extent to which a drug has abuse potential is considered an indication of its public health risk. Based on the preclinical and clinical study data described by HHS (see Factor 2, above), lasmiditan has abuse potential and physical or psychological dependence (Factor 7) that is lower than substances in schedule IV of the CSA and similar to that of substances controlled in schedule V.

7. *Its Psychic or Physiological Dependence Liability:* HHS described an animal study that was conducted to assess the withdrawal effects of lasmiditan. Based on the data from the animal study, HHS concluded that lasmiditan does not produce signs consistent with physical dependence. HHS, in its clarification letter to DEA, stated that animal data, discussed in Factor 2, suggest that lasmiditan has the potential to produce psychological dependence less than that of substances in schedule IV and similar to that of substances in schedule V. HHS further added that these circumstances of uncertain

physical dependence and limited psychological dependence have likewise been observed in their analyses of other schedule V drugs.

8. *Whether the Substance Is an Immediate Precursor of a Substance Already Controlled Under the CSA:* Lasmiditan is not an immediate precursor of a substance that is already controlled in the CSA as defined in 21 U.S.C 802(23).

Conclusion: After considering the scientific and medical evaluation conducted by HHS, HHS' recommendation, and DEA's own eight-factor analysis, DEA has determined that these facts and all relevant data constitute substantial evidence of a potential for abuse of lasmiditan. As such, DEA hereby schedules lasmiditan as a controlled substance under the CSA.

Determination of Appropriate Schedule

21 U.S.C. 812(b) requires the evaluation of a substance's abuse potential, accepted medical use, and safety for use under medical supervision for scheduling under the CSA as a controlled substance. After consideration of the above eight factors determinative of control of a substance (21 U.S.C. 811(c)), and a review of the scientific and medical evaluation and scheduling recommendation provided by HHS, DEA finds that lasmiditan meets the following criteria for placement in schedule V of the CSA pursuant to 21 U.S.C. 812(b)(5).

1) Lasmiditan has a low potential for abuse relative to the drugs or other substances in Schedule IV.

As stated by HHS, lasmiditan, a 5-HT_{1F} receptor agonist, did not bind to receptors typically associated with abuse (*e.g.*, opioid, cannabinoid, GABAergic). In the drug discrimination paradigm, lasmiditan did not generalize to the discriminative stimulus

effects of the benzodiazepine lorazepam. Lasmiditan did, however, produce reinforcing effects in the self-administration assay.

As detailed by HHS, in a human abuse-potential study, all doses of lasmiditan produced drug-liking scores that were significantly higher than that of placebo, indicating its abuse potential. Subjects following lasmiditan reported drug-liking scores that were significantly smaller than that of alprazolam (schedule IV drug), indicating that its abuse potential is less than that of alprazolam. Lasmiditan produced abuse-related adverse events to a greater extent than that of placebo, but with low frequency (about 1 percent).

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

The FDA recently approved the NDA for lasmiditan oral tablets for the acute treatment of migraine with or without aura in adults. Therefore, lasmiditan has a currently accepted medical use in treatment in the United States.

3) Abuse of Lasmiditan may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV.

As stated by HHS, based on the totality of the available scientific data, lasmiditan may lead to physical or psychological dependence that is low relative to substances in schedule IV and similar to that of substances in schedule V.

Based on these findings, the Acting Administrator of DEA concludes that lasmiditan warrants control in schedule V of the CSA. 21 U.S.C. 812(b)(5).

Requirements for Handling Lasmiditan

Lasmiditan is subject to the CSA's schedule V 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 V 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) lasmiditan, or who desires to handle lasmiditan, must be registered with the 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 lasmiditan, and is not registered with the DEA, must submit an application for registration and may not continue to handle lasmiditan, unless the 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 obtain, a schedule V registration must surrender all quantities of currently held lasmiditan, or may transfer all quantities of currently held lasmiditan to a person registered with the DEA in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* Lasmiditan is subject to schedule III–V security requirements and must be handled and stored in accordance with 21 CFR 1301.71–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of lasmiditan 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 lasmiditan must take an inventory of lasmiditan on hand, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who becomes registered with the DEA to handle lasmiditan must take an initial inventory of all stocks of controlled substances (including lasmiditan) 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 lasmiditan) on hand every two years, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

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

7. *Prescriptions.* All prescriptions for lasmiditan, or products containing lasmiditan, 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 V controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of lasmiditan 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 lasmiditan 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 lasmiditan 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 Administrative Procedure Act (APA) (5 U.S.C.) generally requires notice and comment for rulemakings. However, 21 U.S.C. 811 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, 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 final rule is not an Executive Order 13771 regulatory action pursuant to Executive Order 12866 and OMB guidance.[5]

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

[5] 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).

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.

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 $100,000,000 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 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 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), unless otherwise noted.

2. Amend § 1308.15 by:

a. Redesignating paragraph (e)(4) as (e)(5);

b. Adding new paragraph (e)(4).

The addition reads as follows:

§ 1308.15 Schedule V.

* * * * *

(e) * * *

(4) Lasmiditan [2,4,6-trifluoro-*N*-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide]…….……2790

* * * * *

Dated: January 28, 2020.

Uttam Dhillon,
Acting Administrator.

[FR Doc. 2020-01957 Filed: 1/30/2020 8:45 am; Publication Date: 1/31/2020]