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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-581]

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

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule, with request for comments.

SUMMARY: On November 21, 2019, the U.S. Food and Drug Administration (FDA) approved a new drug application for XCOPRI (cenobamate) tablets. Cenobamate is chemically known as [(1R)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl] carbamate. Thereafter, the Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place cenobamate in schedule V of the Controlled Substances Act (CSA). 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 cenobamate, including its salts, 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 pursuant to 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-581" 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/DPW, 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/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Scott Brinks, 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 (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 (HHS) and DEA eight-factor analyses, to this interim final rule are available at *http://www.regulations.gov* for easy reference.

Request for Hearing, Notice of Appearance at 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 (Public Law 114-89), which was signed into law on November 25, 2015, DEA is required to commence an expedited scheduling action with respect to certain new drugs approved by the United States 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 approved 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 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).

Cenobamate is a new molecular entity with CNS depressant properties, and is chemically known as [(1R)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl] carbamate. Cenobamate is a voltage-gated sodium channel (Na_v) blocker that also has gamma-aminobutyric acid (GABA)-A channel positive allosteric modulator (PAM) activity. On November 21, 2018, SK Life Science (Sponsor) submitted an NDA to FDA for XCOPRI (cenobamate) 12.5, 25, 50, 100, 150, and 200 mg oral tablets. On November 22, 2019, DEA received notification from HHS that FDA, on November 21, 2019, approved the NDA for XCOPRI (cenobamate) under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), for the treatment of partial-onset seizures in adult patients.

[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.

Determination to Schedule Cenobamate.

Pursuant to 21 U.S.C. 811(a)(1), proceedings to add a drug or substance to those controlled under the CSA may be initiated by request of the Secretary of HHS.[2] On December 10, 2019, DEA received from HHS a scientific and medical evaluation document (dated December 3, 2019) prepared by FDA, titled "Basis for the Recommendation to Control Cenobamate and Its Salts in Schedule V of the Controlled Substances Act." Pursuant to 21 U.S.C. 811(b) and (c), this document contained an eight-factor analysis of the abuse potential of cenobamate, along with HHS' recommendation to control cenobamate under schedule V of the CSA.

On January 15, 2020, DEA received from HHS a supplemental letter (dated January 15, 2020) clarifying 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), to control cenobamate in schedule V. This letter did not change HHS' overall recommendation to place cenobamate in schedule V.

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 cenobamate 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 HHS recommendation, NDA approval by HHS/FDA, and DEA's determination, DEA is issuing this interim final rule to schedule cenobamate as a schedule V controlled substance under the CSA.

[2] As set forth in a memorandum of understanding entered into by HHS, FDA, and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

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-581." 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:* Cenobamate is a new molecular entity and is not currently available or marketed in any country. Evidence regarding its diversion, illicit manufacturing, or deliberate ingestions is currently lacking. However, as reported by HHS, preclinical studies show that cenobamate shares similar mechanisms of action as substances in schedules IV or V. Cenobamate, like the schedule V substance lacosamide, is a voltage-gated sodium channel (Na_v) blocker. In addition, cenobamate, like the schedule IV substances alprazolam, chlordiazepoxide, and midazolam, has gamma-aminobutyric acid (GABA)-A channel positive allosteric modulator (PAM) activity and increases the effects of the inhibitory neurotransmitter, GABA. Data obtained from general behavioral studies demonstrate that cenobamate produces abuse-related CNS activity. In a preclinical drug discrimination study in rats, cenobamate mimicked the discriminative stimulus effects of the schedule IV substance chlordiazepoxide. However, in a separate drug discrimination study, cenobamate only partially mimicked the discriminative stimulus effects of the schedule IV substance midazolam. In addition, cenobamate, like midazolam, produced reinforcing effects in a rat self-administration assay by significantly increasing the number of infusions compared to saline infusions. In human abuse potential (HAP) studies, cenobamate

produced drug-liking visual analog scale scores that were significantly higher compared to placebo but significantly lower than the schedule IV substance alprazolam. Thus, these studies demonstrate that cenobamate produced behavioral effects in rats comparable to that of schedule IV substances (*i.e.*, similar to chlordiazepoxide but less than midazolam); whereas in humans, cenobamate produced drug-liking effects that were significantly less than that of the schedule IV substance alprazolam. Thus, cenobamate likely has abuse potential less than that of schedule IV substances but similar to that of schedule V substances of the CSA. Based on the totality of the available scientific data, HHS concluded that cenobamate has an abuse potential similar to that of substances in schedule V of the CSA.

2. *Scientific Evidence of Its Pharmacological Effects, if Known:* Cenobamate shares similar mechanisms of action to substances in schedule IV or V and has anti-epileptic activity in humans. Cenobamate, like the schedule V substance lacosamide, is a voltage-gated sodium channel blocker. In addition, cenobamate, like the schedule IV benzodiazepines chlordiazepoxide, midazolam, and alprazolam, is a GABA-A channel positive allosteric modulator. Cenobamate and other GABAergic substances interact directly with the GABA-A receptor which is a ligand-gated chloride ion channel consisting of five subunits and a central chloride channel to enhance the opening of the ligand-gated chloride channel and the influx of chloride. Cenobamate's ability to bind to GABA-A receptors and sodium channel sites is consistent with the action of anti-epileptic or sedative drugs, such as chlordiazepoxide, midazolam, alprazolam, and lacosamide (schedule IV or V substances).

As described in HHS' review document, studies evaluating cenobamate's effect in these general behavioral studies showed that cenobamate mimicked or partially mimicked substances such as chlordiazepoxide, alprazolam, or midazolam (schedule IV substances) in producing behaviors that are associated with abuse. In an *in vivo* drug discrimination study in rats, cenobamate produced chlordiazepoxide-like (schedule IV) discriminative stimulus effects. In a separate drug discrimination study, cenobamate produced discriminative stimulus effects that partially mimicked the effects of the schedule IV substance midazolam. In self-administration studies, cenobamate was self-administered by rodents, but the self-administration (*i.e.*, number of infusions) of cenobamate was lower than that of midazolam, a schedule IV substance. In HAP studies, cenobamate produced drug-liking scores higher than placebo but less than that of the schedule IV substance alprazolam. Based on these studies, HHS concluded that cenobamate has mechanisms of actions that are similar to that of substances in schedule IV or V but the abuse potential of cenobamate is less than that of alprazolam, a schedule IV substance.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* Cenobamate is a new molecular entity. It is chemically known as [(1R)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl] carbamate. Other chemical names for cenobamate include: 2H-tetrazole-2-ethanol, alpha-(2-chlorophenyl)-, carbamate (ester), (alphaR)-; and carbamic acid (R)-(+)-1-(2-chlorophenyl)-2-(2H-tetrazol-2-yl)ethyl ester. It has a molecular formula of $C_{10}H_{10}ClN_5O_2$ and a molecular weight of 267.67 g/mol. Cenobamate is a white to off-white crystalline solid that has a melting point between 96.8–98.3 °C. It is partially soluble in water at a pH between 2 and 12. Pharmacokinetic data indicate that cenobamate is rapidly absorbed, has good bioavailability, and has a

long half-life. Additional studies in humans show that cenobamate is not extensively metabolized and does not produce any major circulating metabolites. On November 21, 2019, FDA approved an NDA for XCOPRI (cenobamate) for the treatment of partial-onset seizures in adult patients. Thus, cenobamate has an accepted medical use in the United States.

4. *Its History and Current Pattern of Abuse:* There is no information on the history and current pattern of abuse for cenobamate, since it has not been marketed, legally or illegally, in any country.

On December 19, 2019, DEA conducted a search on the National Forensic Laboratory Information System (NFLIS)[3] and the STARLiMS[4] databases for cenobamate's encounters. Consistent with the fact that cenobamate is a new molecular entity, these databases had no records of encounters by law enforcement.

The pharmacological activity of cenobamate, like schedule IV or V GABAergic or anti-epileptic substances, at sodium channels and GABA-A receptors suggests that cenobamate's pattern of abuse would be less than that of schedule IV substances but similar to that of schedule V anti-epileptic drugs.

5. *The Scope, Duration, and Significance of Abuse:* Cenobamate is not marketed, legally or illegally, in any country. However, HHS stated that based on the preclinical and clinical study data of cenobamate, the scope, duration, and significance of cenobamate abuse would likely be similar to that of schedule V substances.

[3] NFLIS is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by Federal, State, and local forensic laboratories in the United States.
[4] STARLiMS is a laboratory information management system that systematically collects results from drug chemistry analyses conducted by DEA laboratories. On October 1, 2014, STARLiMS replaced STRIDE as the DEA laboratory drug evidence data system of record.

6. *What, if any, Risk There is to the Public Health:* According to HHS, the public health risk associated with cenobamate is due to its abuse potential. Thus, HHS concluded that the data from preclinical and clinical studies (see Factor 2, above) showed that cenobamate has abuse potential and physical or psychological dependence (Factor 7) similar to that of substances in schedule V.

7. *Its Psychic or Physiological Dependence Liability:* The psychic or physiological dependence liability of drugs can be demonstrated by abuse-related animal and human studies (see Factor 2, above). In animal studies, there were no significant alterations in the withdrawal phase of the study in the measured parameters at either of the tested doses. However, in human studies, cenobamate led to a mild withdrawal syndrome characterized by insomnia, decreased appetite, depressed mood, tremor, and amnesia. Based on these studies, HHS concluded that cenobamate has a psychic or physiological dependence liability similar to that of substances in schedule V.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled under the CSA:* Cenobamate is not an immediate precursor of any substance already controlled in the CSA.

Conclusion: After considering the scientific and medical evaluation conducted by HHS, HHS' recommendation, and its own eight-factor analysis, DEA has determined that these facts and all relevant data constitute substantial evidence of a potential for abuse of cenobamate. As such, DEA hereby schedules cenobamate 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)(5), finds that:

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

Cenobamate, similar to the schedule IV substance lacosamide, is a voltage-gated sodium channel blocker that also has GABA-A channel PAM activity similar to schedule IV benzodiazepines. In drug discrimination studies, cenobamate partially generalized to the discriminative stimulus effects of midazolam (schedule IV) but fully generalized to the discriminative stimulus effects of chlordiazepoxide (schedule IV) in rats. In self-administration studies, cenobamate was self-administered by rodents, but the self-administration (*i.e.*, number of infusions) of cenobamate was lower than that of midazolam. In the HAP studies, cenobamate produced drug-liking scores higher than placebo but less than that of alprazolam, a schedule IV substance. Based on all of these studies, HHS concluded that cenobamate has an abuse potential similar to that of substances in schedule V of the CSA. Thus, DEA finds that the potential for abuse of cenobamate is less than that of schedule IV benzodiazepines but similar to that of substances in schedule V of the CSA.

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

FDA recently approved an NDA for cenobamate as a treatment for partial-onset seizures in adult patients. Thus, cenobamate has a currently accepted medical use in treatment in the United States.

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

HHS reported in Factor 7 that cenobamate may lead to mild withdrawal syndromes characterized by insomnia, decreased appetite, and amnesia in humans. Thus, based on clinical study and preclinical data, HHS concluded in Factor 6 that cenobamate has a physical or psychological dependence liability similar to that of substances controlled in schedule V. In a separate letter, dated January 15, 2020, HHS further stated that based on the totality of available scientific data, cenobamate may lead to physical or psychological dependence that is low relative to substances in schedule IV of the CSA and similar to that of substances in schedule V. Based on these data, DEA finds that the abuse of cenobamate may lead to limited physical or psychological dependence relative to the drugs or other substances in schedule IV.

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

Requirements for Handling Cenobamate.

Cenobamate 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) cenobamate, or who desires to handle cenobamate, must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312. Any person who currently handles or intends to handle cenobamate, and is not registered with DEA, must submit an application for registration and may not continue to handle cenobamate, 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 V registration must surrender all quantities of currently held cenobamate or may transfer all quantities of cenobamate 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.* Cenobamate 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 cenobamate 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 cenobamate must take an inventory of cenobamate 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 cenobamate must take an initial inventory of all stocks of controlled substances (including cenobamate) 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 cenobamate) 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.* DEA registrants must maintain records and submit reports for cenobamate, 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 cenobamate, or products containing cenobamate, 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 cenobamate 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 cenobamate 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 cenobamate 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. 553) 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 interim 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

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),

[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 Regulating and Controlling Regulatory Costs" (Feb. 2, 2017)

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 $100,000,000 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 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 paragraphs (e)(2) through (5) as (e)(3) through (6), respectively;

   b. Adding new paragraph (e)(2).

   The addition reads as follows:

§ 1308.15 Schedule V.

* * * * *

(e) * * *

(2) Cenobamate ([(1R)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl] carbamate; 2*H*-tetrazole-2-ethanol, alpha-(2-chlorophenyl)-, carbamate (ester), (alpha*R*)-; carbamic acid (*R*)-(+)-1-(2-chlorophenyl)-2-(2*H*-tetrazol-2-yl)ethyl ester)…….……..……2720

* * * * *

Dated: March 5, 2020.

Uttam Dhillon,
Acting Administrator.

[FR Doc. 2020-04963 Filed: 3/9/2020 8:45 am; Publication Date: 3/10/2020]