Dated: November 5, 2015.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2015–28552 Filed 11–10–15; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–419F]

Schedules of Controlled Substances: Placement of Eluxadoline Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Administrator of the Drug Enforcement Administration places the substance 5-[[[(*2S*)-2-amino-3-[4-aminocarbonyl)-2,6-dimethylphenyl]-1-oxopropyl][(*1S*)-1-(4-phenyl-1*H*-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid (eluxadoline), including its salts, isomers, and salts of isomers, into schedule IV of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule IV controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities, or possess) or propose to handle eluxadoline.

DATES: *Effective date:* December 17, 2015.

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the ''Controlled Substances Act'' and the ''Controlled Substances Import and Export Act,'' respectively, and are collectively referred to as the ''Controlled Substances Act'' or the ''CSA'' for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of controlled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, ''add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by [21 U.S.C. 812(b)] for the schedule in which such drug is to be placed * * *.'' The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on her own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS); [1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action was initiated at the request of the Assistant Secretary of the HHS and imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule IV controlled substances, on persons who handle or propose to handle eluxadoline.

Background

Eluxadoline (5-[[[(*2S*)-2-amino-3-[4-aminocarbonyl)-2,6-dimethylphenyl]-1-oxopropyl][(*1S*)-1-(4-phenyl-1*H*-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid), is a new molecular entity with central nervous system opioid properties. Eluxadoline has mixed mu opioid receptor (MOR) and kappa opioid receptor (KOR) agonist and delta opioid receptor (DOR) antagonist properties. The Food and Drug Administration (FDA) approved eluxadoline (brand name ''VIBERZI'') as a prescription drug for the treatment of irritable bowel syndrome with diarrhea (IBS–D) on May 27, 2015.

DEA and HHS Eight Factor Analyses

On May 5, 2015, the HHS provided the DEA with a scientific and medical evaluation document prepared by the FDA entitled ''Basis for the Recommendation to Place Eluxadoline in Schedule IV of the Controlled Substances Act.'' After considering the eight factors in 21 U.S.C. 811(c), including consideration of the substance's abuse potential, legitimate medical use, and dependence liability, the Assistant Secretary of the HHS recommended that eluxadoline be controlled in schedule IV of the CSA. In response, the DEA completed its own eight-factor analysis of eluxadoline. Both the DEA and HHS analyses and other relevant documents are available in their entirety in the public docket of this rule (Docket Number DEA–419) at *http://www.regulations.gov* under ''Supporting Documents.'' [2]

Determination to Schedule Eluxadoline

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from the HHS, the Administrator of the DEA published in the **Federal Register** a notice of proposed rulemaking (NPRM) entitled ''Schedules of Controlled Substances: Placement of Eluxadoline into Schedule

[1] As set forth in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the 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 the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993. Accordingly, all subsequent references to ''Secretary'' have been replaced with ''Assistant Secretary.''

[2] Although the published notice of proposed rulemaking stated that such items had been placed into the docket on regulations.gov, the Administration discovered in preparing this final rule that the HHS analysis had in fact not been posted. However, that document was available for review at DEA. The DEA posted the cited analysis to regulations.gov upon discovery of the error.

IV'' which proposed placement of eluxadoline in schedule IV of the CSA. 80 FR 48044, August 11, 2015. The proposed rule provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations by September 10, 2015. No requests for such a hearing were received by the DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposal on or before September 10, 2015.

Comments Received

The DEA received two comments on the proposed rule to schedule eluxadoline. One commenter supported controlling eluxadoline as a schedule IV controlled substance. One commenter opposed the control of eluxadoline as a schedule IV substance, and suggested it be controlled as a schedule V substance instead.

Support for the Proposed Rule. One commenter agreed with the DEA's proposal to control eluxadoline as a schedule IV controlled substance, and stated that the public health (specifically, an unmet medical need) necessitates an immediate effective date for the final order controlling eluxadoline.

DEA Response. The DEA appreciates the comment in support of this rulemaking. Generally, DEA scheduling actions are effective 30 days from the date of publication of the final rule in the **Federal Register**. 21 CFR 1308.45; *see also* 5 U.S.C. 553(d). The DEA believes that providing 30 days for this rule to become effective is both expeditious and sufficient to allow handlers to comply with regulatory requirements for handling Schedule IV controlled substances. Both the HHS' and the DEA's scientific and medical analyses, the data collectively suggest that eluxadoline does have sufficient abuse potential and the DEA does not agree that eluxadoline's effective date should be the date of publication of the final rule.

Opposition to the Proposed Rule. One commenter opposed the proposal to control eluxadoline as a schedule IV controlled substance, stating ''I do not think that eluxadoline meets the factor [5] requirements for scheduling under schedule IV due to there being no general widespread use throughout other countries.'' The commenter also stated that the best approach would be to place eluxadoline in schedule V, rather than schedule IV.

DEA Response. Although eluxadoline is a new chemical entity and information on actual abuse is not currently available, there is a sufficient factual basis to meet the requirements of Factor 5 (the scope, duration, and significance of abuse). The legislative history of the CSA provides guidance regarding the assessment of a new drug's potential for abuse. The legislative history of the CSA provides that a substance may have a potential for abuse if: ''The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.'' Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444 (1970); as reprinted in 1970 U.S.C.C.A.N. 4566, 4601. As discussed in the HHS and the DEA eight-factor analyses, both pre-clinical and clinical studies indicate eluxadoline shares pharmacological similarities with schedule IV drugs such as butorphanol and pentazocine and has similar abuse potential.

In addition, the HHS and DEA eight-factor analyses support the finding that the overall abuse potential of eluxadoline is comparable to schedule IV substances such as pentazocine and butorphanol. This indicates that placement in schedule IV is appropriate rather than schedule V.

Scheduling Conclusion

Based on consideration of all comments, the scientific and medical evaluation and accompanying recommendation of the HHS, and the DEA's consideration of its own eight-factor analysis, the Administrator finds that these facts and all relevant data demonstrate substantial evidence of potential for abuse of eluxadoline. As such, the DEA is scheduling eluxadoline as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA outlines the findings required for placing a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of the HHS and review of all available data, the Administrator of the DEA, pursuant to 21 U.S.C. 812(b)(4), finds that:

(1) 5-[[[(*2S*)-2-amino-3-[4-aminocarbonyl)-2,6-dimethylphenyl]-1-oxopropyl][(*1S*)-1-(4-phenyl-1*H*-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid (eluxadoline) has a low potential for abuse relative to the drugs or other substances in schedule III. The overall abuse potential of eluxadoline is comparable to schedule IV substances such as pentazocine and butorphanol;

(2) 5-[[[(*2S*)-2-amino-3-[4-aminocarbonyl)-2,6-dimethylphenyl]-1-oxopropyl][(*1S*)-1-(4-phenyl-1*H*-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid (eluxadoline) has a currently accepted medical use in treatment in the United States. Recently, the FDA approved eluxadoline as a prescription drug for the treatment of IBS–D. Therefore, eluxadoline has a currently accepted medical use in treatment in the United States; and

(3) Abuse of 5-[[[(*2S*)-2-amino-3-[4-aminocarbonyl)-2,6-dimethylphenyl]-1-oxopropyl][(*1S*)-1-(4-phenyl-1*H*-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid (eluxadoline) may lead to limited psychological dependence similar to that of schedule IV drugs, but less than that of schedule III drugs.

Based on these findings, the Administrator of the DEA concludes that eluxadoline, including its salts, isomers, and salts of isomers, warrants control in schedule IV of the CSA. 21 U.S.C. 812(b)(4).

Requirements for Handling Eluxadoline

Upon the effective date of this final rule, any person who handles eluxadoline is subject to the CSA's schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, engagement in research, and conduct of instructional activities, of schedule IV controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities with) eluxadoline, or who desires to handle eluxadoline, 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 as of December 14, 2015. Any person who currently handles eluxadoline and is not registered with the DEA must submit an application for registration and may not continue to handle eluxadoline as of December 14, 2015 unless the DEA has approved that application, pursuant to 21 U.S.C. 822, 823, 957, and 958, and

in accordance with 21 CFR parts 1301 and 1312.

2. *Security.* Eluxadoline is subject to schedule III–V security requirements and must be handled and stored pursuant to 21 U.S.C. 823 and in accordance with 21 CFR 1301.71–1301.93, as of December 14, 2015.

3. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of eluxadoline must comply with 21 U.S.C. 825 and 958(e) and be in accordance with 21 CFR part 1302, as of December 14, 2015.

4. *Inventory.* Every DEA registrant who possesses any quantity of eluxadoline on the effective date of this final rule must take an inventory of all stocks of eluxadoline on hand as of December 14, 2015, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a), (d), and (e).

Any person who becomes registered with the DEA after November 12, 2015 must take an initial inventory of all stocks of controlled substances (including eluxadoline) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a), (b), and (e).

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including eluxadoline) on hand every two years, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

5. *Records.* All DEA registrants must maintain records with respect to eluxadoline pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304 and 1312 and § 1307.11, as of December 14, 2015.

6. *Prescriptions.* All prescriptions for eluxadoline or products containing eluxadoline must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR part 1306 and subpart C of 21 CFR part 1311 as of December 14, 2015.

7. *Importation and Exportation.* All importation and exportation of eluxadoline must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and be in accordance with 21 CFR part 1312 as of December 14, 2015.

8. *Liability.* Any activity involving eluxadoline not authorized by, or in violation of, the CSA, occurring as of December 14, 2015 is unlawful, and may subject the person to administrative, civil, and/or criminal proceedings.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done ''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 criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform 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

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 the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This rule does not have tribal implications warranting the application of Executive Order 13175. The rule 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 Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. The purpose of this final rule is to place eluxadoline, including its salts, isomers, and salts of isomers, into schedule IV of the CSA. No less restrictive measures (*i.e.,* non-control, or control in schedule V) enable the DEA to meet its statutory obligations under the CSA. In preparing this certification, the DEA has assessed economic impact by size category and has considered costs with respect to the various DEA registrant business activity classes.

Eluxadoline is a new molecular entity which has not yet been marketed in the United States or any other country. The DEA has no basis to determine the level of contracted or outsourced manufacturing activities or the breadth of the distribution network. Furthermore, due to the wide variety of unidentifiable and unquantifiable variables that could potentially influence the dispensing and distribution rates of new pharmaceutical drugs, the DEA is unable to determine the number of potential small entities that might handle eluxadoline. However, the DEA estimates that all persons who would handle, or propose to handle, eluxadoline are currently registered with the DEA to handle schedule IV controlled substances, because it is a pharmaceutical controlled substance intended for medical treatment. Accordingly, the number of DEA registrations authorized to handle schedule IV controlled substances is a reasonable estimate for the maximum number of eluxadoline handlers. Therefore, the DEA estimates that 1.6 million (1,554,254 as of June 2015) controlled substance registrations, representing approximately 427,584 entities, would be the maximum number of entities affected by this final rule. The DEA estimates that 418,141 (97.8%) of 427,584 affected entities are ''small entities'' in accordance with the RFA and SBA size standards.

The DEA anticipates that prospective eluxadoline handlers already handle other schedule IV controlled substances and that the cost impact as a result of placing eluxadoline in schedule IV would be nominal. As the anticipated eluxadoline handlers already handle other schedule IV controlled substances, they already have DEA registrations and the required security and recordkeeping processes, equipment, and facilities in place, and would only require a nominal increase in security, inventory, recordkeeping and labeling costs.

As discussed above, while the DEA does not have a basis to estimate the number of affected entities, the DEA estimates that the maximum number of affected entities is 427,584 of which 418,141 are estimated to be small entities. Since the affected entities are expected to handle other schedule IV controlled substances and maintain security and recordkeeping facilities and processes consistent with schedule IV controlled substances, the DEA estimates any economic impact will be nominal.

Because of these facts, this final rule will not result in a significant economic

impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

The DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.,* 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 for inflation) in any one year * * *'' Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA.

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 section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). 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 United States-based companies to compete with foreign-based companies in domestic and export markets. However, pursuant to the CRA, the DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

Administrative Procedure Act

The APA requires the publication of a substantive rule to be made not less than 30 days before its effective date. 5 U.S.C. 553(d). However, one exception is ''as otherwise provided by the agency for good cause found and published with the rule.'' As fully discussed above in response to the comment suggesting an immediate effective date, an immediate effective date is necessary in this case because there are limited therapeutic options currently available to patients with IBS–D and the eluxadoline NDA received priority review with FDA. Therefore, it is unnecessary to delay the effective date of this final rule by 30 days, and this rule shall take effect immediately upon publication.

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, 21 CFR part 1308 is amended to read 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 § 1308.14 by adding paragraph (g)(3) to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(g) * * *

(3) Eluxadoline (5-[[[(*2S*)-2-amino-3-[4-aminocarbonyl)-2,6-dimethylphenyl]-1-oxopropyl][(*1S*)-1-(4-phenyl-1*H*-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid) (including its optical isomers) and its salts, isomers, and salts of isomers (9725).

Dated: November 5, 2015.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2015–28718 Filed 11–10–15; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 91 and 570

[Docket No. FR 5797–I–01]

RIN 2506–AC39

Changes to Accounting Requirements for the Community Development Block Grants (CDBG) Program

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Interim final rule.

SUMMARY: This rule makes several changes to the existing Community Development Block Grant (CDBG) program regulations in order to better track the use of grant funds and improve accounting procedures in the program. Through this rule, HUD requires grantees to commence tracking the obligations and expenditures of funds for each specific fiscal year grant, rather than track such information cumulatively. In order to effectively implement this accounting change, changes are needed to the regulations applicable to affected grants, such as the program-specific regulations, consolidated plan regulations, and methods to calculate the cap on administrative and planning expenses. While amending these regulations to conform to and support this accounting practice in applicable regulations, HUD is also making certain grammatical and other technical corrections in those regulations.

DATES: *Effective date:* December 14, 2015.

Comment due date: January 11, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this interim rule. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. Submission of Comments by Mail. Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500.

2. Electronic Submission of Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (fax) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m., weekdays, at the