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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-504]

Schedules of Controlled Substances: Placement of Solriamfetol in Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule adopts, without change, an interim final rule with request for comments published in the *Federal Register* on June 17, 2019, placing solriamfetol (2-amino-3-phenylpropyl carbamate), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule IV of the Controlled Substances Act. With the issuance of this final rule, the Drug Enforcement Administration maintains solriamfetol, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule IV of the CSA.

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

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

The Improving Regulatory Transparency for New Medical Therapies Act (Public Law 114-89) was signed into law on November 25, 2015. This law amended the Controlled Substances Act (CSA) and states that in cases where the Drug Enforcement Administration (DEA) receives notification from The Department of Health and Human Services (HHS) that the Secretary has approved an application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), the DEA is required to issue an interim final rule, with opportunity for public comment and to request a hearing, controlling the drug not later than 90 days after receiving such notification from HHS and subsequently to issue a final rule. 21 U.S.C. 811(j). When controlling a drug pursuant to section 811(j), the DEA must apply the scheduling criteria of subsections 811(b), (c), and (d) and section 812(b). 21 U.S.C. 811(j)(3).

Solriamfetol (2-amino-3-phenylpropyl carbamate) is a new molecular entity with central nervous system (CNS) stimulant properties. Solriamfetol primarily acts as a dopamine and norepinephrine reuptake inhibitor and does not bind to any other receptors that are typically associated with abuse, such as opioid or cannabinoid receptors, GABAergic, and other ion channels. On December 20, 2017, Jazz Pharmaceuticals, Inc. (Sponsor) submitted a new drug application (NDA) to the Food and Drug Administration (FDA) for SUNOSI (solriamfetol) 75 and 150 mg oral tablets. On March 19, 2019, DEA received from HHS a scientific and medical evaluation document (dated March 8, 2019) prepared by the FDA related to solriamfetol. Pursuant to 21 U.S.C. 811(b), this document contained an eight-factor analysis of the abuse potential of solriamfetol, along with HHS' recommendation to control solriamfetol under schedule IV of the CSA. Subsequently, on March 20, 2019, the DEA received notification that the FDA, on that same date,

approved the NDA for SUNOSI (solriamfetol), under section 505(c) of the FDCA, to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).

On June 17, 2019, the DEA published an interim final rule [84 FR 27943] to make solriamfetol (including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible) a schedule IV controlled substance. Interested persons were provided a 30 day comment period in which to submit comments on this rulemaking in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.43(g). In addition, interested persons were provided an opportunity to file a request for hearing or waiver of hearing pursuant to 21 U.S.C. 811(j)(3) and 21 CFR 1308.44. The deadline for submitting comments or requests for hearing/waiver of hearing was July 17, 2019. The DEA received one comment and did not receive any requests for hearing or waiver of hearing.

Comments Received

In response to the interim final rule, the DEA received one comment. The commenter indicated that all clinical studies on solriamfetol are supported by the sponsor of the NDA for solriamfetol and thus subject to conflicts of interests. This commenter further stated that long-term adverse health effects (including adverse effects on the cardiovascular system) of solriamfetol have not been studied and such effects need to be considered.

> DEA Response: The comment relating to the alleged conflicts of interests as a result of financial support of the clinical studies by the sponsor of the NDA and the long-term toxicity of solriamfetol are related to the FDA approval process (such as weighing the benefits versus risks of approving the drug for the proposed

indication) and are outside of the scope of this rulemaking because they do not relate to the factors determinative of control of a substance (21 U.S.C. 811(c)). The DEA notes that the FDA approved an NDA for solriamfetol and provided the DEA with a scheduling recommendation for solriamfetol. The scheduling recommendation by HHS and its notification to DEA regarding the FDA approval of the NDA initiated the DEA review and scheduling action. As stated in the interim final rule, after careful consideration of data from preclinical and clinical studies, the DEA concurred with the HHS recommendation that solriamfetol has abuse potential comparable to other schedule IV stimulants and therefore supported – and continues to support through this final rule – placement of solriamfetol in schedule IV under the CSA.

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

Requirements for Handling Solriamfetol

As indicated above, solriamfetol has been a schedule IV controlled substance by virtue of the interim final rule issued by DEA in June 2019. Thus, this final rule does not alter the regulatory requirements applicable to handlers of solriamfetol that have been in place since that time. Nonetheless, for informational purposes, we restate here those requirements. Solriamfetol is subject to the CSA's schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importing, exporting, research, and conduct of instructional activities and chemical analysis with, and possession involving schedule IV substances, including, but not limited to, the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) solriamfetol, or who desires to handle solriamfetol, 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 intends to handle solriamfetol, and is not registered with the DEA, must submit an application for registration and may not handle solriamfetol, unless the DEA approves that application for registration, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person who obtains a schedule IV registration to handle solriamfetol but who subsequently does not desire or is not able to maintain such registration must surrender all quantities of solriamfetol, or may transfer all quantities of solriamfetol 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.* Solriamfetol 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 solriamfetol 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 solriamfetol was required to keep an inventory of solriamfetol on hand, as of June 17, 2019, 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 solriamfetol, or products containing solriamfetol, 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 solriamfetol or products containing solriamfetol must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

8. *Manufacturing and Distributing*. In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule IV controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of solriamfetol 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 solriamfetol 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 solriamfetol not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Administrative Procedure Act

This final rule, without change, affirms the amendment made by the interim final rule that is already in effect. Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553) generally requires notice and comment for rulemakings. However, 21

U.S.C. 811 provides that in cases where a new drug is (1) approved by HHS and (2) HHS recommends control in CSA schedule II-V, the 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 the DEA to demonstrate good cause. The DEA issued an interim final rule on June 17, 2019 and solicited public comments on that rule. Section 811 further states that after giving interested persons the opportunity to comment and to request a hearing, "the Attorney General shall issue a final rule in accordance with the scheduling criteria of subsections (b), (c), and (d) of this section and section 812(b) of" the CSA. 21 U.S.C. 811(j)(3). The DEA is now responding to the comment submitted by the public and issuing the final rule, in conformity with the APA and the procedure required by 21 U.S.C. 811.

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulatory 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.[1]

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 final rule does not have federalism implications warranting the application of Executive Order 13132. The final rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This final rule does not have tribal implications warranting the application of 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),

[1] 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 DEA was not required to publish a general notice of proposed rulemaking prior to this final rule. 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.*, the DEA has determined and certifies that this action would not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year." Therefore, neither a Small Government Agency Plan nor any other action is required under 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 final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This rule will not result in an annual effect on the economy of $100,000,000 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, the DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

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

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

Accordingly, the interim final rule amending 21 CFR part 1308, which published on June 17, 2019 (84 FR 27943), is adopted as a final rule without change.

Dated: December 17, 2019

Uttam Dhillon,
Acting Administrator.
[FR Doc. 2019-27955 Filed: 1/6/2020 8:45 am; Publication Date: 1/7/2020]