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 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, the 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 § 1308.14 by:
■ a. Redesignating paragraphs (c)(4) through (c)(55) as (c)(5) through (c)(56);
■ b. Adding new paragraph (c)(4).
The addition reads as follows:

§ 1308.14 Schedule IV.

* * * * *

(c) * * *

(4) Brexanolone	2400

* * * * *

Dated: June 10, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019–12721 Filed 6–14–19; 8:45 am]

BILLING CODE 4410–09–P

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: Interim final rule, with request for comments.

SUMMARY: On March 20, 2019, the U.S. Food and Drug Administration approved a new drug application for SUNOSI, a drug product consisting of solriamfetol ((*R*)-2-amino-3-phenylpropyl carbamate hydrochloride) tablets for oral use. Thereafter, the Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place solriamfetol in schedule IV 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 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 rulemaking is June 17, 2019. 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 July 17, 2019. 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 July 17, 2019.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–504'' 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: Lynnette M. Wingert, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

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.

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, 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).

Background

On December 20, 2017, Jazz Pharmaceuticals, Inc. (Sponsor) submitted an NDA to FDA for SUNOSI (solriamfetol) 75 and 150 mg oral tablets. FDA determined that solriamfetol is a new molecular entity, and HHS determined that solriamfetol has a stimulant effect on the central nervous system. On March 20, 2019, FDA approved the NDA for SUNOSI (solriamfetol) to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).

Determination To Schedule Solriamfetol

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, DEA received notification from HHS that the FDA had approved an NDA for SUNOSI (solriamfetol).

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 solriamfetol met the 21 U.S.C. 812(b)(4) criteria for placement in schedule IV of the CSA.

Pursuant to subsection 811(j)—and based on the HHS recommendation, NDA approval by HHS/FDA, and DEA's determination—the DEA is issuing this interim final rule to schedule solriamfetol as a schedule IV controlled substance under the CSA.

Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in its scheduling action. Please note that both 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 ''DEA–504.'' 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:* Solriamfetol is a new molecular entity that has not been marketed in the United States or any other country. Thus, information about the diversion and actual abuse of solriamfetol is limited. Solriamfetol is currently not available for medical treatment, has not been diverted from legitimate sources, and individuals have not taken this substance in amounts sufficient to create a hazard to public health and safety. The DEA notes that there are no reports for solriamfetol in the National Forensic Laboratory Information System (NFLIS),[2] which collects drug

[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.

[2] The National Forensic Laboratory Information System (NFLIS) represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS is a comprehensive information system that includes data from forensic

identification results from drug cases submitted to and analyzed by state and local forensic laboratories. There were also no reports in STARLiMS,[3] DEA's laboratory drug evidence data system of record.

As stated by HHS, solriamfetol is a stimulant that has low affinity for the human dopamine, serotonin, and norepinephrine transporters. In a clinical study investigating the abuse potential of solriamfetol, HHS concluded that solriamfetol produced subjective responses that were similar to those for the schedule IV stimulant phentermine.

2. *Scientific Evidence of Its Pharmacological Effects, if Known:* 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. According to HHS, general behavioral studies in animals indicate that solriamfetol produces stimulant effects such as an increase in locomotor activity and anorexic effects. However, in drug discrimination studies used to predict subjective effects in humans, solriamfetol at doses that do not severely impact motor responses did not mimic stimulus effects of schedule II substances amphetamine or cocaine. In a human abuse potential study, therapeutic doses of solriamfetol produced feelings of relaxation, hypervigilance, elevated mood, insomnia, and hyperhidrosis. These adverse events (AEs) are consistent with those of stimulant drugs and are also seen with phentermine, a schedule IV substance. In other clinical studies, adverse events such as anxiety, insomnia, and agitation were seen in subjects treated with solriamfetol. HHS concluded that the results from animal and human studies indicate that solriamfetol has low abuse potential similar to phentermine.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* Solriamfetol is a new molecular entity, chemically known as (*R*)-2-amino-3-phenylpropyl carbamate. It has a molecular formula of $C_{10}H_{14}N_2O_2$. Solriamfetol is a white to off-white solid that has a melting point between 183–189 °C. It is highly soluble in water at a pH between one and seven. On March 20, 2019, the FDA approved an NDA for solriamfetol for medical use to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or OSA. Thus, solriamfetol has an accepted medical use in the United States. Solriamfetol will be marketed as a once daily tablet and is available in strengths of 75 and 150 mg. The 75 mg tablet is functionally scored to permit a starting dose for patients with OSA of 37.5 mg once daily.[4]

4. *Its History and Current Pattern of Abuse:* There is no information available relating to the history and current pattern of abuse of solriamfetol, since this drug is not currently marketed in any country. HHS notes that solriamfetol produces abuse-related signals and abuse potential similar to that of schedule IV controlled substance phentermine.

The DEA conducted a search on the NFLIS and STARLiMS databases for solriamfetol encounters. Consistent with the fact that solriamfetol is a new molecular entity, these databases had no records of encounters of solriamfetol by law enforcement.

5. *The Scope, Duration, and Significance of Abuse:* Solriamfetol as a single active ingredient in a drug product is currently not marketed in any country. Thus, information on the scope, duration, and significance of abuse for solriamfetol is lacking. However, as HHS notes, data from preclinical and clinical studies summarized in factor 2 and epidemiological data indicate that the scope, duration, and significance of abuse for solriamfetol would be similar to those of phentermine, a schedule IV substance. As stated by HHS, data from animal and human studies indicate that solriamfetol has abuse potential similar to phentermine.

6. *What, if any, Risk There is to the Public Health:* The extent of abuse potential of a drug is an indication of its public health risk. Data from the preclinical and clinical studies suggest that the abuse potential and physical or psychological dependence of solriamfetol are similar to schedule IV substances such as phentermine.

7. *Its Psychic or Physiological Dependence Liability:* Physical dependence for solriamfetol was tested in animal toxicity studies and during Phase 3 clinical trials. According to HHS, animal toxicity studies in rats and dogs demonstrated no symptoms of withdrawal from discontinuation of the solriamfetol. In clinical studies, sudden cessation of solriamfetol produced a low percentage of adverse events that HHS concluded did not exhibit a consistent pattern of withdrawal symptoms. Based on these studies, HHS stated that solriamfetol does not appear to cause physical dependence.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled under the CSA:* Solriamfetol is not an immediate precursor of any controlled substance, as defined in 21 U.S.C. 802(23).

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

Determination of Appropriate Schedule

The CSA outlines 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 the DEA, pursuant to 21 U.S.C. 812(b)(4), finds that:

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

Receptor binding and functional studies demonstrate that solriamfetol acts as a dopamine and norepinephrine reuptake inhibitor that does not appear to bind to other receptors typically associated with abuse (*e.g.,* opioid, cannabinoid, GABAergic, and other ion channels). Results from animal behavioral studies (using solriamfetol treated animals) demonstrated increases in locomotor activity, increases in awake time in the sleep-wake cycle, and anorexia, all of which may be indicative of abuse potential of solriamfetol. However, in drug discrimination studies used to predict subjective effects in humans, solriamfetol did not produce full generalization to cocaine or amphetamine. In a human abuse potential study, subjects treated with solriamfetol experienced adverse events

laboratories that handle more than 96% of an estimated 1.0 million distinct annual state and local drug analysis cases. NFLIS includes drug chemistry results from completed analyses only. While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* 76 FR 77330, 77332, Dec. 12, 2011. NFLIS data were queried 04/02/2019.

[3] On October 1, 2014, the DEA implemented STARLiMS (a web-based, commercial laboratory information management system) to replace the System to Retrieve Information from Drug Evidence (STRIDE) as its laboratory drug evidence data system of record. DEA laboratory data submitted after September 30, 2014, are reposited in STARLiMS. STARLiMS data were queried on 04/02/2019.

[4] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211230s000lbl.pdf,* accessed May 6, 2019.

that were similar to that of the schedule IV stimulant phentermine. In phase 1 through 3 clinical trials, solriamfetol treated subjects exhibited low rates of adverse effects including insomnia, anxiety, and agitation. The data from preclinical and clinical studies indicate that solriamfetol has a low potential for abuse relative to other substances in schedule III. Solriamfetol has abuse potential similar to phentermine.

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

The FDA recently approved solriamfetol to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea. Thus, solriamfetol has a currently accepted medical use in the United States.

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

In animal toxicology studies, rats or dogs exposed to solriamfetol demonstrated no indication of physical dependence after abrupt discontinuation of the drug. This is consistent with the effects of amphetamine-like stimulant drugs, which produce psychological dependence, but little or no physical dependence. In clinical studies, subjects receiving solriamfetol reported an array of adverse events after discontinuation from the drug. However, there was no consistent pattern of withdrawal symptoms that would indicate physical dependence. In a human abuse potential study, solriamfetol increased drug liking scores that are significantly greater than that of placebo and are similar to or less than that of phentermine. These data collectively suggest that solriamfetol abuse may lead to limited psychological dependence relative to drugs in schedule III and largely similar to that of schedule IV stimulants.

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

Requirements for Handling Solriamfetol

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 currently handles or intends to handle solriamfetol, and is not registered with DEA, must submit an application for registration and may not continue to handle solriamfetol, unless DEA has approved the application for registration, pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person who does not desire or is not able to maintain a schedule IV registration must surrender all quantities of currently held solriamfetol, or may transfer all quantities of currently held solriamfetol to a person registered with DEA in accordance with 21 CFR part 1317, in additional to all other applicable federal, state, local, and tribal laws.

3. *Security.* Solriamfetol is subject to schedule III–V security requirements and must be handled and stored in accordance with 21 CFR 1301.71–93.

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 must take an inventory of all stocks of solriamfetol 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 solriamfetol must take an initial inventory of all stocks of controlled substances containing solriamfetol 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 solriamfetol) 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 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

Public Law 114–89 was signed into law, amending 21 U.S.C. 811. This amendment provides that in cases where a 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. Therefore, DEA has determined that the notice and comment requirements of section 553 of the APA, 5 U.S.C. 553, do not apply to this scheduling action.

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 Public Law 114–89, 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

In accordance with 5 U.S.C. 603(a), ''[w]henever an agency is required by [5 U.S.C. 553], or any other law, to publish general notice of proposed rulemaking for any proposed rule, or publishes a notice of proposed rulemaking for an interpretive rule involving the internal revenue laws of the United States, the agency shall prepare and make available for public comment an initial regulatory flexibility analysis.'' As noted in the above discussion regarding applicability of the APA, the DEA has determined that the notice and comment requirements of section 553 of the APA, 5 U.S.C. 553, do not apply to this scheduling action. Consequently, the Regulatory Flexibility Act 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 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 does 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 does 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 § 1308.14 by:
■ a. Redesignating paragraph (f)(12) as (f)(13);
■ b. Adding new paragraph (f)(12).
The addition to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(f) * * *

(12) Solriamfetol (2-amino-3-phenylpropyl car-bamate; benzenepropanol, beta-amino-, carbamate (ester))	1650

* * * * *

Dated: June 10, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019–12723 Filed 6–14–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9863]

RIN 1545–BO50

Modification of Discounting Rules for Insurance Companies

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations on discounting rules for unpaid losses and estimated salvage recoverable of insurance companies for Federal income tax purposes. The final regulations update and replace existing regulations to implement recent legislative changes to the Internal Revenue Code (Code) and make a technical improvement to the derivation of loss payment patterns used for discounting. The final regulations affect entities taxable as insurance companies.

DATES:

Effective Date: These regulations are effective June 17, 2019.

Applicability Date: For dates of applicability, see § 1.846–1(e)(2).

FOR FURTHER INFORMATION CONTACT: Kathryn M. Sneade, (202) 317–6995 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to 26 CFR part 1 under section 846 of the Code. Section 846 was added to the Code by section 1023(c) of the Tax Reform Act of 1986, Public Law 99–514 (100 Stat. 2085, 2399). Final regulations under section 846 were published in the **Federal Register** (57 FR 40841) on

[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).