



## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA-808]

#### Schedules of Controlled Substances: Placement of Serdexmethylphenidate in

#### Schedule IV

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Interim final rule with request for comments.

**SUMMARY:** On March 2, 2021, the United States Food and Drug Administration approved a new drug application for AZSTARYS capsules for oral use, a combination drug product containing serdexmethylphenidate chloride and dexamethylphenidate hydrochloride, for the treatment of Attention Deficit Hyperactivity Disorder in patients six years of age or older. The Department of Health and Human Services provided the Drug Enforcement Administration with a scheduling recommendation to place serdexmethylphenidate and its salts in schedule IV of the Controlled Substances Act. In accordance with the Controlled Substances Act, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, Drug Enforcement Administration is hereby issuing an interim final rule placing serdexmethylphenidate, including its salts, isomers, and salts of isomers, in schedule IV of the Controlled Substances Act, thereby facilitating the commercial distribution of AZSTARYS as a lawful controlled substance.

**DATES:** The effective date of this rulemaking is [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Interested persons may file written comments on this rulemaking in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons may file a request for hearing or waiver of hearing in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.44. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing, together with a written statement of position on the matters of fact and law asserted in the 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-808” on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration (DEA) 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 Morrisette Drive, Springfield, VA 22152.

- *Hearing requests:* All requests for hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

**FOR FURTHER INFORMATION CONTACT:** Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362-3249.

**SUPPLEMENTARY INFORMATION:** This interim final rule refers to the single entity, serdexmethylphenidate. The chloride salt of serdexmethylphenidate is chemically known as 3-[[[(1S)-1-carboxy-2-hydroxyethyl]-amino]carbonyl]-1-[[[(2R)-2-[(1R)-2-methoxy-2-oxo-1-phenylethyl]-1-piperidiny]carbonyl]oxy]methyl]pyridinium chloride. This rule places serdexmethylphenidate, including its salts, isomers, and salts of isomers, in schedule IV of the Controlled Substances Act (CSA), thereby facilitating the commercial distribution of AZSTARYS as a controlled substance.

### **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 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 or Waiver of Participation in a 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. Such requests or notices must conform to the requirements of 21 CFR 1308.44(a) or (b), and 1316.47 or 1316.48, as applicable, and include a statement of the person’s interests in the proceeding and the objections or

issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c) and may include a written statement regarding the interested person's position on the matters of fact and law involved in any hearing.

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 CSA, as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (section 2(b) of Pub. Law 114-89), DEA is required to commence an expedited scheduling action with respect to certain new drugs approved by the 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 HHS has advised DEA that a New Drug Application (NDA) has been submitted for a drug that has a stimulant, depressant, or hallucinogenic effect on the central nervous system (CNS), and that it appears that such drug has an abuse potential; and (2) the Secretary of HHS 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.

Subsection (j)(2) 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. Subsection (j)(3) specifies that the rulemaking shall become immediately effective as an interim final rule without requiring DEA to demonstrate good cause therefore. 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.<sup>1</sup>

Subsection (j)(3) 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 21 U.S.C. 811(b) through (d) and 812(b).

Serdexmethylphenidate chloride (3-[[[(1S)-1-carboxy-2-hydroxyethyl]-amino]carbonyl]-1-[[[(2R)-2-[(1R)-2-methoxy-2-oxo-1-phenylethyl]-1-piperidinyl]carbonyl]oxy]methyl]pyridinium chloride) is a new molecular entity (NME) without CNS activity. However, according to HHS, because serdexmethylphenidate chloride (SDX) is metabolized in the large intestine to dexamethylphenidate (*d*-MPH), a schedule II drug and a CNS stimulant, SDX is a prodrug of *d*-MPH.

On March 2, 2020, Commave Therapeutics S.A. submitted an NDA to FDA, in partnership with KemPharm, Inc., for a combination drug product containing SDX and *d*-MPH, both as chloride salts. On March 2, 2021, DEA received notification that FDA, on the same date, approved this NDA for AZSTARYS capsules for oral use, a combination drug product containing dexamethylphenidate hydrochloride and serdexmethylphenidate chloride, under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients six years of age or older. According to the FDA-approved product label, AZSTARYS contains 28mg/6mg, 42mg/9mg, or 56mg/12 mg of serdexmethylphenidate chloride/dexamethylphenidate hydrochloride (equivalent to 26.1 mg/5.2 mg, 39.2 mg/7.8 mg, and 52.3 mg/10.4 mg of serdexmethylphenidate/dexamethylphenidate, respectively)<sup>2</sup>.

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<sup>1</sup> 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.

<sup>2</sup> [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/212994s0001bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212994s0001bl.pdf).

The 90-day time frame, as stipulated to in subsection 811(j)(2) and discussed above, was triggered on March 2, 2021. Therefore, DEA must issue an interim final rule controlling serdexmethylphenidate on or before May 31, 2021.

### **Determination to Schedule Serdexmethylphenidate**

On March 2, 2021, DEA received from HHS a scientific and medical evaluation entitled “Basis for the Recommendation to Control Serdexmethylphenidate and its Salts in schedule IV of the Controlled Substances Act” and a scheduling recommendation. Pursuant to 21 U.S.C. 811(b) and (c), this document contained an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of serdexmethylphenidate, along with HHS’s recommendation to control serdexmethylphenidate and its salts under schedule IV of the CSA.

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 pursuant to 21 U.S.C. 811(c). DEA concluded that SDX meets 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 HHS’ scheduling recommendation, the approval of the NDA by HHS/FDA, and DEA’s determination, DEA is issuing this interim final rule to schedule SDX 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 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-808.” 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*

SDX is an NME that has not been marketed in the United States or any country. Thus, evidence regarding its diversion and actual abuse is lacking. SDX only recently became 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. DEA notes that there are no reports for SDX in the National Forensic Laboratory Information System (NFLIS),<sup>3</sup> which collects drug cases submitted to and analyzed by state and local forensic laboratories.

As stated by HHS, clinical studies show that SDX, when taken by the oral route, produces effects that are similar to other stimulant drugs in schedule IV, such as phentermine. The pharmacological mechanism of action of SDX is based on its prodrug characteristics, as it must be metabolized to *d*-MPH to exert its effects. In clinical studies, SDX demonstrated a lower potential for abuse when compared to *d*-MPH and similar potential for abuse when compared to phentermine. This evidence demonstrates that SDX is related in action and effect to the schedule IV substance phentermine, and can therefore be expected to have a similar potential for abuse.

## 2. *Scientific Evidence of Its Pharmacological Effects, if Known*

SDX itself has no CNS activity and must be metabolized to *d*-MPH to exert its effect. As HHS notes, *in vitro* binding studies demonstrated that SDX does not interact with dopamine and norepinephrine transporters, which are the sites of action for *d*-MPH, a schedule II drug. Moreover, SDX does not bind to any other receptor systems that are associated with drugs of abuse.

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<sup>3</sup> 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 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 on March 4, 2021.



In a human abuse potential (HAP) study, therapeutic and suprathreshold doses of SDX administered orally produced positive subjective responses such as Drug Liking and Drug High similar to those of phentermine and higher than placebo. In addition, abuse-related adverse events such as euphoric mood and hypervigilance occurred less frequently in SDX-treated subjects than in those treated with *d*-MPH. However, SDX-treated subjects reported more abuse-related adverse events than those treated with placebo. As concluded by HHS, results from preclinical and clinical studies indicate that SDX has abuse potential similar to phentermine, a schedule IV substance.

### *3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance*

SDX is an NME. It is chemically known as 3-[[[(1*S*)-1-carboxy-2-hydroxyethyl]-amino]carbonyl]-1-[[[(2*R*)-2-[(1*R*)-2-methoxy-2-oxo-1-phenylethyl]-1-piperidinyl]carbonyl]oxy]methyl]pyridinium chloride. It is a white to off-white crystalline solid that is freely soluble in water at pH that was tested up to 6.8. On March 2, 2021, FDA approved the NDA for AZSTARYS, a combination drug product containing *d*-MPH and SDX for the treatment of ADHD in patients six years of age or older. Thus, SDX has an accepted medical use in the United States. SDX will be marketed in combination with *d*-MPH (SDX/*d*-MPH) as immediate-release capsules in three strengths of 28 mg/6 mg, 42 mg/9 mg, and 56 mg/12 mg.

### *4. Its History and Current Pattern of Abuse*

There is no information on the history and current pattern of abuse for SDX, since it has not been marketed, legally or illegally, in the United States. HHS notes that SDX produces abuse-related signals, such as euphoric mood and hypervigilance, and abuse potential similar to that of schedule IV controlled substance phentermine. In March 2021, DEA searched the NFLIS database for SDX encounters. Consistent with the fact

that SDX is an NME, this database had no records of encounters of SDX by law enforcement.

#### *5. The Scope, Duration, and Significance of Abuse*

SDX is not marketed in the United States, legally or illegally. Thus, information on the scope, duration, and significance of abuse for SDX is lacking. However, as stated by HHS, data from animal and human studies indicate that SDX has abuse potential similar to phentermine. Therefore, upon marketing, SDX scope of abuse is expected to be 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 preclinical and clinical studies showed that SDX has abuse potential similar to that of the schedule IV stimulant phentermine. Therefore, upon availability for marketing, SDX is likely to pose a public health risk to a degree similar to schedule IV stimulants, such as phentermine.

#### *7. Its Psychic or Physiological Dependence Liability*

As HHS notes, no animal studies were done to test physical dependence liability of SDX. A hallmark of physical dependence are withdrawal symptoms resulting from drug discontinuation. In clinical studies, there was no adverse events indicative of withdrawal from discontinuation of the SDX/d-MPH combination treatment.

SDX produced positive subjective responses to ratings of Drug Liking and Drug High in a HAP study. The responses were significantly higher than the placebo and similar to phentermine, a schedule IV stimulant. HHS concluded that SDX can produce psychic dependence to a similar extent as phentermine.

*8. Whether the Substance is an Immediate Precursor of a Substance Already Controlled under the CSA*

SDX is not an immediate precursor of any controlled substance, as defined by 21 U.S.C. 802(23).

*Conclusion:* After considering the scientific and medical evaluation and scheduling recommendation provided by HHS, and its own eight-factor analysis, DEA has determined that these facts and all relevant data constitute substantial evidence of potential for abuse of SDX. As such, DEA hereby schedules SDX 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)(4), finds that:

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

Receptor binding studies demonstrate that SDX does not bind to dopamine and norepinephrine transporters and other receptors typically associated with abuse potential. Upon oral administration, SDX is metabolized to *d*-MPH, a schedule II drug, in the large intestine and showed an abuse potential lower than that of *d*-MPH, but similar to that of phentermine, a schedule IV drug. Results from an observational animal behavioral study demonstrate that lower doses of SDX (12 and 25 mg/kg) did not produce any CNS effects and only the highest dose of SDX (50 mg/kg) increased CNS activity. In a HAP study, SDX at the therapeutic and supra-therapeutic doses produced positive subjective responses such as Drug Liking and Drug High similar to those of phentermine (schedule IV) and significantly higher than placebo. Furthermore, data from other clinical studies show that SDX produced abuse-related adverse events, namely euphoric mood and

hypervigilance. Because SDX is similar to phentermine (schedule IV) in its abuse potential, SDX has a lower potential for abuse relative to the drugs or other substances in schedule III.

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

On March 2, 2021, FDA approved the NDA for AZSTARYS capsules, a combination drug product containing *d*-MPH and SDX for the treatment of ADHD in patients six years of age or older. Thus, SDX has a currently accepted medical use for treatment in the United States.

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

There were no animal studies performed to evaluate physical dependence of SDX. In clinical studies, SDX demonstrated no indication of physical dependence after abrupt discontinuation of the drug. In a HAP study, SDX increased drug-liking scores that were significantly greater than that of placebo and were similar to that of phentermine. In addition, SDX produced euphoria-related adverse events in a HAP study. These data collectively suggest that SDX 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 SDX warrants control in schedule IV of the CSA. 21 U.S.C. 812(b)(4).

### **Requirements for Handling Serdexmethylphenidate**

Serdexmethylphenidate 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 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), or who desires to handle, serdexmethylphenidate, 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 serdexmethylphenidate and is not registered with DEA must submit an application for registration and may not continue to handle serdexmethylphenidate 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. These registration requirements, however, are not applicable to patients (end users) who possess serdexmethylphenidate pursuant to a lawful prescription.

2. *Disposal of stocks.* Any person who obtains a schedule IV registration to handle serdexmethylphenidate but who subsequently does not desire or is not able to maintain such registration must surrender all quantities of serdexmethylphenidate or may transfer all quantities of serdexmethylphenidate 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.* Serdexmethylphenidate is subject to schedule III-V security requirements for DEA registrants and it must be handled and stored in accordance with 21 CFR 1301.71-1301.77. Non-practitioners handling serdexmethylphenidate must also comply with the employee screening requirements of 21 CFR 1301.90-1301.93. These requirements, however, are not applicable to patients (end users) who possess serdexmethylphenidate pursuant to a lawful prescription.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of serdexmethylphenidate 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 serdexmethylphenidate must take an inventory of serdexmethylphenidate 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 serdexmethylphenidate must take an initial inventory of all stocks of controlled substances (including serdexmethylphenidate) 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 serdexmethylphenidate) 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. These requirements, however, are not applicable to patients (end users) who possess serdexmethylphenidate pursuant to a lawful prescription.

6. *Records and Reports.* DEA registrants must maintain records and submit reports for serdexmethylphenidate, pursuant to 21 U.S.C. 827, 832(a), and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317.

7. *Prescriptions.* All prescriptions for serdexmethylphenidate, or products containing serdexmethylphenidate, 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 serdexmethylphenidate may only be for the legitimate purposes consistent with the drug's labeling, or for research activities authorized by the FDCA and CSA.

9. *Importation and Exportation.* All importation and exportation of serdexmethylphenidate 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 serdexmethylphenidate 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 APA (5 U.S.C. 553) generally requires notice and comment for rulemakings. However, 21 U.S.C. 811(j) provides that in cases where a certain new drug is (1) approved by HHS, under section 505(c) of the FDCA and (2) HHS recommends control in CSA schedule II-V, DEA shall issue an interim final rule scheduling the drug within 90 days. As stated in the legal authority section, the 90-day time frame is the later of: (1) the date DEA receives HHS's scientific and medical evaluation/scheduling recommendation, or (2) the date DEA receives notice of the NDA approval by HHS. Additionally, subsection (j) specifies that the rulemaking shall become immediately effective as an interim final rule without requiring DEA to demonstrate good cause.

### *Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)*

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 (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

*Executive Order 12988, Civil Justice Reform*

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 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 E.O. 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 E.O. 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. As noted in the above discussion regarding the applicability of the APA, 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. However, pursuant to the CRA, DEA is submitting 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), 956(b) unless otherwise noted.

2. In § 1308.14:

- a. Redesignate paragraphs (f)(11) through (13) as (f)(12) through (14); and
- b. Add new paragraph (f)(11).

The addition reads as follows:

**§ 1308.14 Schedule IV.**

\* \* \* \* \*

(f) \* \* \*

(11) Serdexmethylphenidate.....1729

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**D. Christopher Evans,**

*Acting Administrator*

[FR Doc. 2021-09738 Filed: 5/6/2021 8:45 am; Publication Date: 5/7/2021]