Commerce (Secretary) to designate, manage, and protect, as a national marine sanctuary, any area of the marine environment that is of special national significance due to its conservation, recreational, ecological, historical, scientific, cultural, archeological, educational, or esthetic qualities (16 U.S.C. 1431 *et seq.*). NMSA provides the legal basis and serves as the authority under which NOAA issues this action.

Nicole R. LeBoeuf,

Assistant Administrator for Ocean Services and Coastal Zone Management, National Ocean Service.

[FR Doc. 2022–13570 Filed 6–23–22; 8:45 am]

BILLING CODE 3510–NK–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1234

[Docket No. CPSC–2015–0019]

Safety Standard for Infant Bath Tubs

AGENCY: Consumer Product Safety Commission.

ACTION: Direct final rule.

SUMMARY: In March 2017, the U.S. Consumer Product Safety Commission (CPSC) published a consumer product safety standard for infant bath tubs under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA). The standard incorporated by reference the 2017 ASTM voluntary standard for infant bath tubs that was in effect at the time. The CPSIA sets forth a process for updating mandatory standards for durable infant or toddler products that are based on a voluntary standard, when the voluntary standards organization revises the standard. Consistent with the CPSIA's update process, the Commission issued a direct final rule in October 2018, that revised the incorporation by reference for the mandatory standard for infant bath tubs to reflect ASTM's revised 2018 voluntary standard. Also consistent with the CPSIA's update process, this direct final rule again updates the mandatory standard for infant bath tubs to incorporate by reference ASTM's 2022 version of the voluntary standard.

DATES: The rule is effective on September 24, 2022, unless CPSC receives a significant adverse comment by July 25, 2022. If CPSC receives such a comment, it will publish a document in the **Federal Register**, withdrawing this direct final rule before its effective date. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of September 24, 2022.

ADDRESSES: You can submit comments, identified by Docket No. CPSC–2015–0019, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *https://www.regulations.gov.* Follow the instructions for submitting comments. CPSC does not accept comments submitted by electronic mail (email), except *as described below.* CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal.

Mail/Hand Delivery/Courier Written Submissions: Submit comments by mail/hand delivery/courier to: Division of the Secretariat, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; telephone: (301) 504–7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: *cpsc-os@cpsc.gov.*

Instructions: All submissions must include the agency name and docket number for this direct final rule. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: *https://www.regulations.gov.* Do not submit electronically: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier written submissions.

Docket: For access to the docket to read background documents or comments received, go to: *https://www.regulations.gov,* and insert the docket number, CPSC–2015–0019, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Salman Sarwar, Compliance Officer, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; telephone: (301) 504–7682; email: *ssarwar@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

1. Statutory Authority

Section 104(b)(1) of the CPSIA requires the Commission to assess the effectiveness of voluntary standards for durable infant or toddler products and to adopt mandatory standards for these products. 15 U.S.C. 2056a(b)(1). A mandatory standard must be ''substantially the same as'' the corresponding voluntary standard, or it may be ''more stringent than'' the voluntary standard, if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the product. *Id.*

Section 104(b)(4)(B) of the CPSIA specifies the process for updating the Commission's rules when a voluntary standards organization revises a standard that the Commission previously incorporated by reference under section 104(b)(1). First, the voluntary standards organization must notify the Commission of the revision. Once the Commission receives this notification, the Commission may reject or accept the revised standard. The Commission may reject the revised standard by notifying the voluntary standards organization, within 90 days of receiving notice of the revision, that it has determined that the revised standard does not improve the safety of the consumer product and that it is retaining the existing standard. If the Commission does not take this action to reject the revised standard, the revised voluntary standard will be considered a consumer product safety standard issued under section 9 of the Consumer Product Safety Act (15 U.S.C. 2058), effective 180 days after the Commission received notification of the revision or on a later date specified by the Commission in the **Federal Register**. 15 U.S.C. 2056a(b)(4)(B).

2. Safety Standard for Infant Bath Tubs

Under section 104(b)(1) of the CPSIA, the Commission adopted a mandatory rule for infant bath tubs, codified in 16 CFR part 1234. The rule incorporated by reference ASTM F2670–17, *Standard Consumer Safety Specification for Infant Bath Tubs,* with no modifications. 82 FR 15615 (March 30, 2017). At the time the Commission published the final rule, ASTM F2670–17 was the current version of the voluntary standard.

In July 2018, ASTM notified CPSC that it had issued a revised standard for infant bath tubs, ASTM F2670–18. The Commission concluded that the revisions improved the safety of infant bath tubs. As such, in accordance with the procedures set out in section 104(b)(4)(B) of the CPSIA, the revised standard became the new mandatory standard for infant bath tubs. The Commission published a direct final

rule to update 16 CFR part 1234, incorporating by reference ASTM F2670–18, with no modifications. 83 FR 53371 (Oct. 23, 2018).

On March 28, 2022, ASTM notified CPSC that it has again revised the voluntary standard for infant bath tubs, by approving ASTM F2670–22 on March 1, 2022.[1] As discussed in section B. Revisions to ASTM F2670, based on CPSC staff's review of ASTM F2670–22,[2] the Commission will allow the revised voluntary standard to become the mandatory standard because it improves the safety of infant bath tubs.[3] Accordingly, by operation of law under section 104(b)(4)(B) of the CPSIA, ASTM F2670–22 will become the mandatory consumer product safety standard for infant bath tubs on September 24, 2022. 15 U.S.C. 2056a(b)(4)(B). This direct final rule updates 16 CFR part 1234 to incorporate by reference the revised voluntary standard, ASTM F2670–22.

B. Revisions to ASTM F2670

The ASTM standard for infant bath tubs includes performance requirements, test methods, and requirements for warning labels and instructional literature, to address hazards to children associated with infant bath tubs. ASTM F2670–22 contains substantive revisions as well as editorial, non-substantive revisions. Revisions to the standard includes changes to language in the standard describing latching and locking mechanisms (*i.e.,* mechanisms that prevent the product from folding or collapsing in a manner that puts the occupant at risk) and new marking, labeling, warning, and instructional requirements addressing battery-powered infant bath tubs. This section describes the changes in ASTM F2670–22, as compared to ASTM F2670–18, which is the current mandatory standard, and includes an assessment of those changes.

1. Substantive Revisions

a. General Requirements

The general requirement subsection *Resistance to Collapse* has been renamed *Latching and Locking Mechanism(s).* Section 5.4.1 has been edited to state that products that fold must have a latching and locking mechanism(s) or other means to prevent the product from folding or collapsing in a manner that puts the occupant at risk of injury by falling out of the product or being subjected to contact or pressure by product components. The standard states that ''other means'' can include, but are not limited to, designs that utilize the occupant, an added component, or the water that is placed into the product to act in opposition to the folding action or collapse of the product. Latching and locking mechanisms are subject to the same general and performance requirements as required in 16 CFR part 1234 (some non-substantive changes have been made to these requirements).

These changes improve safety, because 16 CFR part 1234 currently does not explicitly require folding infant bath tubs or infant bath tub accessories to have latching and locking mechanisms or ''other means'' of preventing the product from folding or collapsing.

b. Marking and Labeling

Revisions to the 2022 standard include the addition of specific marking requirements for products that are battery-operated. Currently, 16 CFR part 1234 does not contain any marking and labeling requirements specifically addressing battery-powered infant bath tubs. Section 8.4.1 of the 2022 standard states that the product's battery compartment, battery compartment door/cover, or area immediately adjacent to the battery compartment must be marked or labeled permanently and legibly to show the correct battery polarity, size, and voltage. Products utilizing one or more non-replaceable batteries are exempt from this requirement. However, Section 8.4.2 states that products utilizing one or more non-replaceable batteries accessible with the use of a coin, screwdriver, or other common household tool shall be marked or labeled permanently and legibly with a statement that the batteries are not replaceable. If marking or labeling the product is not practicable, then this statement shall be in the instructions.

In addition to on-product marking/labeling requirements, ASTM F2670–22 now includes specific warning requirements for battery-powered infant bath tubs and infant bath tub accessories packaging. Section 8.11 states that packages of infant bath tubs and infant bath tub accessories that use replaceable button or coin cell batteries that are 1.5 V or greater and that are larger than 15 mm in diameter but fit within the small parts cylinder (see 16 CFR 1501) shall include the following warning:

WARNING

Contains button or coin cell battery. Hazardous if swallowed—see instructions. This warning is subject to the formatting requirements found in section 8.5, which contains no substantive changes.

The changes in this section improve safety, as they address battery ingestion hazards, which are not currently addressed by 16 CFR part 1234.

c. Instructional Literature

The requirements for instructional literature in ASTM F2670–22 now include cautionary and warning statements specifically for battery-operated products, which are not addressed in 16 CFR part 1234. Section 9.4 *Cautionary and Warning Statements* now requires that products that operate using replaceable batteries include the following:

CAUTION

To prevent battery leaks, which can burn skin and eyes:

- Remove batteries when storing product for a long time.
- Dispose of used batteries immediately.

Products that use more than one battery in any one circuit must also include the following statements under the same CAUTION header:

- Always replace the entire set of batteries at one time.
- Never mix old and new batteries, or batteries of different brands or types.

These changes improve safety, as they address burn hazards caused by battery leaks, which are not currently addressed by 16 CFR part 1234.

2. Non-Substantive Revisions

ASTM F2670–22 also includes several non-substantive changes, such as spacing and formatting. ASTM also revised the language in the introduction and removed CPSIA from its list of referenced documents to bring the standard into alignment with current Ad Hoc Recommended Language.[4] These changes to the text and formatting do not materially affect the safety of infant bath tubs.

[1] ASTM also published ASTM F2670–22 in March 2022.

[2] CPSC staff's briefing package regarding ASTM F2670–22 is available at: *https://www.cpsc.gov/s3fs-public/ASTMs-Revised-Safety-Standard-for-Infant-Bath-Tubs.pdf?VersionId=xRDuGZaaWMa44CPG5rG2jwa0VdYy5c4M.*

[3] The Commission voted 3–0–1 to approve this notice. Chair Hoehn-Saric, Commissioners Feldman and Trumka voted to approve the notice as drafted. Commissioner Baiocco did not vote.

[4] ASTM convened a task group, ASTM Ad Hoc Wording Task Group (Ad Hoc TG), consisting of members of the various durable nursery products voluntary standards committees, including CPSC staff. The purpose of the Ad Hoc TG is to harmonize the wording, as well as the warning format, across durable infant and toddler product voluntary standards. Ad Hoc TG recommendations were published as a reference document, titled, ''Ad Hoc Wording—May 4, 2016,'' as part of the F15 Committee Documents.

C. Incorporation by Reference

Section 1234.2 of the direct final rule incorporates by reference ASTM F2670–22. The Office of the Federal Register (OFR) has regulations regarding incorporation by reference. 1 CFR part 51. Under these regulations, agencies must discuss, in the preamble to a final rule, ways in which the material the agency incorporates by reference is reasonably available to interested parties, and how interested parties can obtain the material. In addition, the preamble to the final rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR regulations, section B. Revisions to ASTM F2670 of this preamble summarizes the major provisions of ASTM F2670–22 that the Commission incorporates by reference into 16 CFR part 1234. The standard is reasonably available to interested parties. Until the direct final rule takes effect, a read-only copy of ASTM F2670–22 is available for viewing, at no cost, on ASTM's website at: *https://www.astm.org/CPSC.htm.* Once the rule takes effect, a read-only copy of the standard will be available for viewing, at no cost, on the ASTM website at: *https://www.astm.org/READINGLIBRARY/.* Interested parties can also schedule an appointment to inspect a copy of the standard at CPSC's Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East-West Highway, Bethesda, MD 20814, telephone: (301) 504–7479; email: *cpsc-os@cpsc.gov.* Interested parties can purchase a copy of ASTM F2670–22 from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959 USA; telephone: (610) 832–9585; *www.astm.org.*

D. Certification

Section 14(a) of the Consumer Product Safety Act (CPSA; 15 U.S.C. 2051–2089) requires manufacturers of products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, to certify that the products comply with all applicable CPSC requirements. 15 U.S.C. 2063(a). Such certification must be based on a test of each product, or on a reasonable testing program, or for children's products, on tests of a sufficient number of samples by a third party conformity assessment body accredited by CPSC to test according to the applicable requirements. As noted, standards issued under section 104(b)(1)(B) of the CPSIA are ''consumer product safety standards.'' Thus, they are subject to the testing and certification requirements of section 14 of the CPSA.

Because infant bath tubs are children's products, a CPSC-accepted third party conformity assessment body must test samples of the products. Products subject to part 1234 also must comply with all other applicable CPSC requirements, such as the lead content requirements in section 101 of the CPSIA,[5] the tracking label requirements in section 14(a)(5) of the CPSA,[6] and the consumer registration form requirements in section 104(d) of the CPSIA.[7] ASTM F2670–22 makes no changes that would impact any of these existing requirements.

E. Notice of Requirements

In accordance with section 14(a)(3)(B)(vi) of the CPSA, the Commission previously published a notice of requirements (NOR) for accreditation of third party conformity assessment bodies for testing infant bath tubs. 82 FR 15615 (March 30, 2017). The NOR provided the criteria and process for CPSC to accept accreditation of third party conformity assessment bodies for testing infant bath tubs to 16 CFR part 1234. The NORs for all mandatory standards for durable infant or toddler products are listed in the Commission's rule, ''Requirements Pertaining to Third Party Conformity Assessment Bodies,'' codified in 16 CFR part 1112. *Id.*

ASTM F2670–22 did not change the testing requirements, testing equipment, or testing protocols for infant bath tubs. Accordingly, the revisions do not change the way that third party conformity assessment bodies test these products for compliance with the safety standard for infant bath tubs. Testing laboratories that have demonstrated competence for testing in accordance with ASTM F2670–18 therefore are competent to test in accordance with the revised standard ASTM F2670–22. Laboratories will begin testing to the new standard when ASTM F2670–22 goes into effect, and the existing accreditations that the Commission has accepted for testing to this standard will cover testing to the revised standard. Therefore, the Commission considers the existing CPSC-accepted laboratories for testing to ASTM F2670–18 to be capable of testing to ASTM F267–22 as well. Accordingly, the existing NOR for this standard will remain in place, and CPSC-accepted third party conformity assessment bodies are expected to update the scope of the testing laboratories' accreditations to reflect the revised standard in the normal course of renewing their accreditations.

F. Direct Final Rule Process

The Commission is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA; 5 U.S.C. 551–559) generally requires agencies to provide notice of a rule and an opportunity for interested parties to comment on it, section 553 of the APA provides an exception when the agency ''for good cause finds'' that notice and comment are ''impracticable, unnecessary, or contrary to the public interest.'' *Id.* 553(b)(B). The Commission concludes that when it updates a reference to an ASTM standard that the Commission incorporated by reference under section 104(b) of the CPSIA, notice and comment are not necessary.

Specifically, under the process set out in section 104(b)(4)(B) of the CPSIA, when ASTM revises a standard that the Commission has previously incorporated by reference under section 104(b)(1)(B) of the CPSIA, that revision will become the new CPSC standard, unless the Commission determines that ASTM's revision does not improve the safety of the product. Thus, unless the Commission makes such a determination, the ASTM revision becomes CPSC's standard by operation of law. The Commission is allowing ASTM F2670–22 to become CPSC's new standard because its provisions improve product safety. The purpose of this direct final rule is to update the Code of Federal Regulations (CFR) so that it reflects the version of the standard that takes effect by statute. This rule updates the reference in the CFR, but under the terms of the CPSIA, ASTM F2670–22 takes effect as the new CPSC standard for infant bath tubs, even if the Commission does not issue this rule. Thus, public comments would not alter substantive changes to the standard or the effect of the revised standard as a consumer product safety standard under section 104(b) of the CPSIA. Under these circumstances, notice and comment are unnecessary.

In Recommendation 95–4, the Administrative Conference of the United States (ACUS) endorses direct final rulemaking as an appropriate procedure to expedite rules that are noncontroversial and not expected to generate significant adverse comments. *See* 60 FR 43108 (Aug. 18, 1995). ACUS recommends that agencies use the direct final rule process when they act under the ''unnecessary'' prong of the good cause exemption in 5 U.S.C. 553(b)(B). Consistent with the ACUS recommendation, the Commission is publishing this rule as a direct final

[5] 15 U.S.C. 1278a.

[6] 15 U.S.C. 2063(a)(5).

[7] 15 U.S.C. 2056a(d).

rule, because CPSC does not expect any significant adverse comments.

Unless CPSC receives a significant adverse comment within 30 days of this notification, the rule will become effective on September 24, 2022. In accordance with ACUS's recommendation, the Commission considers a significant adverse comment to be ''one where the commenter explains why the rule would be inappropriate,'' including an assertion challenging ''the rule's underlying premise or approach,'' or a claim that the rule ''would be ineffective or unacceptable without a change.'' 60 FR 43108, 43111 (Aug. 18, 1995). As noted, this rule merely updates a reference in the CFR to reflect a change that occurs by statute, and public comments should address this specific action.

If the Commission receives a significant adverse comment, the Commission will withdraw this direct final rule. Depending on the comment and other circumstances, the Commission may then incorporate the adverse comment into a subsequent direct final rule or publish a notice of proposed rulemaking, providing an opportunity for public comment.

G. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA; 5 U.S.C. 601–612) generally requires agencies to review proposed and final rules for their potential economic impact on small entities, including small businesses, and prepare regulatory flexibility analyses. 5 U.S.C. 603, 604. The RFA applies to any rule that is subject to notice and comment procedures under section 553 of the APA. *Id.* As discussed in section F. Direct Final Rule Process of this preamble, the Commission has determined that notice and the opportunity to comment are unnecessary for this rule. Therefore, the RFA does not apply. CPSC also notes the limited nature of this document, which merely updates the incorporation by reference to reflect the mandatory CPSC standard that takes effect under section 104 of the CPSIA.

H. Paperwork Reduction Act

The current mandatory standard for infant bath tubs includes requirements for marking, labeling, and instructional literature that constitute a ''collection of information,'' as defined in the Paperwork Reduction Act (PRA; 44 U.S.C. 3501–3521). While the revised mandatory standard adds additional marking, labeling, and instructional literature language for battery-powered infant bath tubs, the new requirements would not add to the burden hours because the products already require marking, labeling, and instructional literature. The new requirements merely require a small amount of labeling language in addition to that already required by the standard, for infant bath tubs using batteries. Therefore, the new requirements are not measurably more burdensome than the existing requirements. The Commission took the steps required by the PRA for information collections when it promulgated 16 CFR part 1234, and the marking, labeling, and instructional literature for infant bath tubs are currently approved under OMB Control Number 3041–0159. Because the information collection burden is unchanged, the revision does not affect the information collection requirements or approval related to the standard.

I. Environmental Considerations

The Commission's regulations provide a categorical exclusion for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement where they ''have little or no potential for affecting the human environment.'' 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

J. Preemption

Section 26(a) of the CPSA provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. 15 U.S.C. 2075(a). Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to CPSC for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA deems rules issued under that provision ''consumer product safety standards.'' Therefore, once a rule issued under section 104 of the CPSIA takes effect, it will preempt in accordance with section 26(a) of the CPSA.

K. Effective Date

Under the procedure set forth in section 104(b)(4)(B) of the CPSIA, when a voluntary standards organization revises a standard that the Commission adopted as a mandatory standard, the revision becomes the CPSC standard within 180 days of notification to the Commission, unless the Commission timely notifies the standards organization that it has determined that the revision does not improve the safety of the product, or the Commission sets a later date in the **Federal Register**. 15 U.S.C. 2056a(b)(4)(B). The Commission is taking neither of those actions with respect to the standard for infant bath tubs. Therefore, ASTM F2670–22 will take effect as the new mandatory standard for infant bath tubs on September 24, 2022, 180 days after March 28, 2022, when the Commission received notice of the revision.

L. Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801–808) states that before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The CRA submission must indicate whether the rule is a ''major rule.'' The CRA states that the Office of Information and Regulatory Affairs determines whether a rule qualifies as a ''major rule.''

Pursuant to the CRA, this rule does not qualify as a ''major rule,'' as defined in 5 U.S.C. 804(2). To comply with the CRA, CPSC will submit the required information to each House of Congress and the Comptroller General.

List of Subjects in 16 CFR Part 1234

Consumer protection, Imports, Incorporation by reference, Imports, Infants and children, Law enforcement, Safety, Toys.

For the reasons discussed in the preamble, the Commission amends 16 CFR chapter II as follows:

PART 1234—SAFETY STANDARD FOR INFANT BATH TUBS

■ 1. The authority citation for part 1234 continues to read as follows:

Authority: The Consumer Product Safety Improvement Act of 2008, Pub. L. 110–314, 104, 122 Stat. 3016 (August 14, 2008); Pub. L. 112–28, 125 Stat. 273 (August 12, 2011).

■ 2. Revise § 1234.2 to read as follows:

§ 1234.2 Requirements for Infant Bath Tubs.

Each infant bath tub must comply with all applicable provisions of ASTM F2670–22, *Standard Consumer Safety Specification for Infant Bath Tubs,* approved on March 1, 2022. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A read-only copy of the standard is available for viewing on the ASTM website at *https://www.astm.org/*

READINGLIBRARY/. You may obtain a copy from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959; telephone (610) 832–9585; *www.astm.org.* You may inspect a copy at the Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East-West Highway, Bethesda, MD 20814, telephone (301) 504–7479, email *cpsc-os@cpsc.gov,* or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Alberta E. Mills,

Secretary Consumer Product Safety Commission.

[FR Doc. 2022–13255 Filed 6–23–22; 8:45 am]

BILLING CODE 6355–01–P

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: Final rule.

SUMMARY: This final rule adopts, without change, an interim final rule with request for comments published in the **Federal Register** on May 7, 2021, placing serdexmethylphenidate, including its salts, isomers, and salts of isomers, in schedule IV of the Controlled Substances Act.

DATES: Effective July 25, 2022.

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

SUPPLEMENTARY INFORMATION: This final rule refers to the single entity, serdexmethylphenidate. The chloride salt of serdexmethylphenidate 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. This rule maintains the placement of 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.

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. L. 114–89), when the Drug Enforcement Administration (DEA) receives notification from the Department of Health and Human Services (HHS) that the Secretary has approved a certain new drug and HHS recommends control in the CSA schedule II–V, DEA is required to issue an interim final rule (IFR), with opportunity for public comment and to request a hearing, controlling the drug within a specified 90-day timeframe and to subsequently issue a final rule. 21 U.S.C. 811(j). When controlling a drug pursuant to subsection (j), DEA must apply the scheduling criteria of 21 U.S.C. 811(b) through (d) and 812(b). 21 U.S.C. 811(j)(3).

On March 2, 2021, DEA received notification that the United States Food and Drug Administration approved, on that same date, a new drug application for AZSTARYS capsules for oral use, a combination drug product containing serdexmethylphenidate chloride (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) and dexmethylphenidate hydrochloride, for the treatment of Attention Deficit Hyperactivity Disorder in patients six years of age or older. In addition, on that same date, HHS recommended that DEA place serdexmethylphenidate in schedule IV of the CSA. On May 7, 2021, DEA, pursuant to 21 U.S.C. 811(j), published an IFR to place serdexmethylphenidate (including its salts, isomers, and salts of isomers) in schedule IV. 86 FR 24487. The IFR provided an opportunity for interested persons to submit comments, as well as file a request for hearing or waiver of hearing, on or before June 7, 2021. DEA did not receive any requests for hearing or waiver of hearing.

Comments Received

In response to the IFR, DEA received seven comments. The submissions were from individuals or anonymous commenters. Four of the seven commenters were in support of the IFR to place serdexmethylphenidate in schedule IV of the CSA and one commenter was opposed to the placement of serdexmethylphenidate in schedule IV of the CSA. Of the two remaining comments, one had no relevant content and the other was against the scheduling of drugs in general and did not specifically comment on serdexmethylphenidate. This latter commenter associated the scheduling of substances with the ''war on drugs,'' which according to the commenter ''has failed.'' No response is necessary for the former comment and the latter comment is outside the scope of this current scheduling action and, therefore, these comments will not be addressed.

Support of the Interim Final Rule

Four commenters supported controlling serdexmethylphenidate as a schedule IV controlled substance. These commenters indicated support for scheduling serdexmethylphenidate under the CSA due to its similarity to phentermine, a schedule IV substance. Three of the commenters also recommended monitoring serdexmethylphenidate for increased public health risk or undertaking more clinical research to determine its long-term effects, but did not specify who should perform this monitoring or research. One of these commenters expressed concern about the misuse, including overprescribing, and abuse of stimulant medications in general, and believes that additional prevention measures are needed besides just placing the drug in schedule IV.

DEA Response. DEA appreciates the support for this rulemaking. The requests for additional research or prevention measures suggested by the commenters are outside of DEA's purview. Therefore, DEA has no response to these requests.

Opposition to the Interim Final Rule

One commenter opposed the IFR to control serdexmethylphenidate as a schedule IV drug. The commenter's primary issue with the scheduling of serdexmethylphenidate was that, as a new drug, there was no documented evidence of abuse potential. While the commenter did not completely disagree with the placement of serdexmethylphenidate in schedule IV, the commenter suggested that DEA should ''let scientists experiment with it first to determine if it has any beneficial use'' or if serdexmethylphenidate is more effective for controlling Attention Deficit Hyperactivity Disorder compared to current drug treatments. Thus, the commenter thought DEA should only schedule serdexmethylphenidate if problems occur. The commenter also referred to ongoing clinical studies for