Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sarah Venti, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *drugtrackandtrace@fda.hhs.gov;* or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs.'' The DSCSA (title II of Pub. L. 113–54) was signed into law on November 27, 2013. Section 202 of the DSCSA added section 582 to the FD&C Act (21 U.S.C. 360eee–1), which established the requirement that trading partners have systems in place to enable them to comply with certain verification obligations. This guidance provides recommendations for robust verification systems for the determination, quarantine, and investigation of suspect products, as well as the quarantine, notification, and disposition of illegitimate products. This guidance also addresses the manner in which FDA recommends that trading partners submit cleared product notifications (*i.e.,* notifications that a suspect product is not an illegitimate product), the statutory requirements for responding to requests for verification, and the statutory requirements for processing saleable returns.

FDA initially published the draft guidance ''Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs'' on October 25, 2018 (83 FR 53880). Comments were received on the initial draft guidance and the Agency made revisions to the draft. This guidance finalizes the revised draft guidance entitled ''Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs,'' issued on March 10, 2022 (87 FR 13738). FDA considered comments received on the revised draft guidance in finalizing this guidance. Changes from the revised draft to the final guidance include: (1) clarifying that dispensers need not provide transaction information for saleable return product; (2) clarifying that ''verification'' as defined in section 581 of the FD&C Act (21 U.S.C. 360eee) involves confirming that the product identifier affixed or imprinted upon a package or homogeneous case corresponds to the Standardized Numerical Identifier or lot number and expiration date assigned to the product by the manufacturer or repackager by more closely mirroring the statutory language; (3) further clarifying when the discussion is about the verification systems requirements in section 582 of the FD&C Act and when it is about the requirement to verify the product identifier; (4) clarifying FDA's understanding about the statutory requirement that manufacturers and repackagers respond to requests for verification within 24 hours or within other such reasonable time as determined by the Secretary of Health and Human Services; (5) clarifying that when a trading partner does not receive a timely response to a verification request, the product that is the subject of the request need not automatically be classified as suspect; and (6) clarifying that certain system attributes are suggested as best practices even though they are not specifically required under the DSCSA. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information pertaining to implementation of the Drug Supply Chain Security Act are approved in OMB control no. 0910–0806.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26846 Filed 12–6–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3517]

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under section 503A of the Federal Food, Drug, and Cosmetic Act'' (draft guidance or 2023 503A Interim Policy Draft Guidance) to describe FDA's interim policy regarding the use of bulk drug substances by human drug compounders that are not registered with FDA as outsourcing facilities while FDA develops the list of bulk drug substances that can be used in compounding under the applicable section of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This draft guidance, when finalized, will replace the guidance for industry entitled, ''Interim Policy on Compounding Using Bulk Drug Substances under section 503A of the Federal Food, Drug, and Cosmetic Act'' issued in January 2017 (2017 503A Interim Policy Guidance).

DATES: Submit either electronic or written comments on the draft guidance by January 8, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–3517 for ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Mariestela Buhay, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 5199, Silver Spring, MD 20993–0002, 301–796–7313.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under section 503A of the Federal Food, Drug, and Cosmetic Act.'' This draft guidance, when finalized, will replace the 2017 503A Interim Policy Guidance, available at *https://www.fda.gov/media/94398/download.* Section 503A of the FD&C Act (21 U.S.C. 353a) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FD&C Act: (1) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice requirements). One of the conditions that must be met for a compounded drug product to qualify for these exemptions is that a licensed pharmacist or licensed physician compounds the drug product using bulk drug substances that (1) comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapters on pharmacy compounding; (2) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary of the Department of Health and Human Services (Secretary); or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list developed by the Secretary through regulations issued by the Secretary under subsection (c) of section 503A of the FD&C Act (the 503A bulks list). (See section 503A(b)(1)(A)(i) of the FD&C Act.)

This draft guidance, when finalized, will revise FDA's current interim policy with respect to categorization of certain substances nominated for inclusion on the 503A bulks list. The guidance, when finalized, will end the categorization of bulk drug substances into Categories 1, 2, or 3 for those bulk drug substances nominated on or after the date of publication of the final guidance.

The 2017 503A Interim Policy Guidance describes the conditions under which FDA does not intend to take action against a State-licensed pharmacy, Federal facility, or physician for compounding drug products using certain bulk drug substances that are not eligible for use in compounding under

section 503A because they are not the subject of an applicable USP or NF monograph, components of FDA-approved drug products, or on the 503A bulks list. One of those conditions is that the bulk drug substance appears in Category 1. If the 2023 503A Interim Policy Draft Guidance is finalized in its current form, a substance nominated on or after the date of publication of that final guidance would not be categorized and would not be within the scope of the policy for substances that appear in Category 1.[1] However, FDA would consider the substance for inclusion on the 503A bulks list in accordance with the process and criteria established in the FD&C Act and FDA regulations (see section 503A(b)(1)(A) of the FD&C Act and 21 CFR 216.23(c)). Substances that already appear in Category 1 (including substances nominated with adequate supporting information prior to the date of publication of the final guidance) may continue to be eligible for the policy that applies to Category 1 substances, as described in the final guidance, until FDA promulgates a final rule determining whether they will be placed on the 503A bulks list in accordance with section 503A(b)(1)(A)(i)(III) of the FD&C Act or unless the Agency removes the substances from Category 1 based on, for example, information about safety risks.

FDA encourages interested parties to focus their comments on the limited revisions to the interim policy included, for public comment, in the 2023 503A Interim Policy Draft Guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26886 Filed 12–6–23; 8:45 am]

BILLING CODE 4164–01–P

[1] FDA recognizes that some compounders and other stakeholders may currently be in the process of compiling a nomination for the 503A bulks list for submission to the Agency. FDA intends to categorize nominations of bulk drug substances received prior to the date in which FDA announces the availability of the final guidance. FDA believes that this will provide a sufficient amount of time in which to submit nominations that are currently in progress.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: The Alliance for Innovation on Maternal Health Biannual Survey, OMB No. 0915–xxxx—New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than February 5, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: The Alliance for Innovation on Maternal Health Biannual Survey, OMB No. 0915–xxxx—New.

Abstract: The Alliance for Innovation on Maternal Health (AIM) program is administered by HRSA and authorized by 42 U.S.C. 254c–21 (Public Health Service Act, title III section 330O), as added by the Consolidated Appropriations Act, 2022 (Pub. L. 117–103).

The AIM program supports the identification, development, implementation, and dissemination of maternal (patient) safety bundles to promote safe care for every U.S. birth and assist with addressing the complex problem of high maternal mortality and severe maternal morbidity rates within the U.S. The mission of AIM is to support best practices that make birth safer, improve the quality of maternal health care and outcomes, and save lives. Maternal patient safety bundles address topics commonly associated with health complications or risks related to prenatal, labor and delivery, and postpartum care.

The AIM program consists of two components: The AIM Capacity program and the AIM Technical Assistance (TA) Center. The AIM Capacity awards began in fiscal year 2023 and directly fund 28 States and jurisdictions (including U.S. Territories and the District of Columbia) to implement AIM maternal patient safety bundles. The second component, the AIM TA Center, is funded through a cooperative agreement to provide TA to all 50 States, the District of Columbia, jurisdictions, U.S. Territories, Tribal communities, and birthing facilities who participate in the AIM program. The TA Center builds data capacity for participating entities to track progress on bundle implementation and support improvement of data collection.

The funding amount for the AIM program was increased in fiscal year 2023, which allowed HRSA to directly fund States and Territories to support AIM bundle implementation. Previously, HRSA supported AIM through one cooperative agreement to develop maternal patient safety bundles, provide TA on bundle implementation, and enroll States and Territories in the program. The shift to directly fund States and jurisdictions for the work makes the collection of information about the reach of the program, participation by birthing facilities, and TA needs necessary. The AIM Biannual Survey will be administered to AIM State Teams (the State-or jurisdiction-level entity leading AIM implementation) twice a year in all States and jurisdictions enrolled in