DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–65 and CMS–10142]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Correction

In notice document 2024–30444 beginning in the third column on page 104182 in the issue of Friday, December 20, 2024, make the following correction:

On page 104182, in the third column, under the **DATES** section, replace the text [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**] with ''January 21, 2025''.

[FR Doc. C1–2024–30444 Filed 1–6–25; 8:45 am]

BILLING CODE 0099–10–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Refugee Resettlement

Statement of Organization, Functions, and Delegations of Authority; Delegation From Office of Refugee Resettlement Director to Unaccompanied Children Bureau Chief

Notice is hereby given that I delegate to the Chief of the Unaccompanied Children Bureau the following authority delegated to the Deputy Assistant Secretary for Humanitarian Services and Director of the Office of Refugee Resettlement by the Assistant Secretary for Children and Families and the Secretary under the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (Pub. L. 110–457 sec. 235, amended).

(a) Authority Delegated

Authority under the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 section 235(d)(1) to specifically consent to juvenile court jurisdiction for an unaccompanied alien child who is applying for special immigrant status pursuant to the Immigration and Nationality Act (8 U.S.C. 1101 (a)(27)(J)) and who is in the custody of the Secretary.

(b) Limitations

1. This delegation shall be exercised under the Department's existing delegation of authority and policy on regulations.

2. This delegation shall be exercised under financial and administrative requirements applicable to all Administration for Children and Families authorities.

(c) Effective Date

This delegation of authority is effective on date of signature. In addition, I hereby affirm and ratify any actions taken by the Chief of the Unaccompanied Children Bureau, which, in effect, involved the exercise of these authorities prior to the effective date of this delegation.

Robin Dunn Marcos,

Deputy Assistant Secretary for Humanitarian Services and Director, Office of Refugee Resettlement.

[FR Doc. 2025–00004 Filed 1–6–25; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3539]

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act; 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 final guidance for industry entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' This guidance describes FDA's interim regulatory policy concerning compounding by outsourcing facilities using bulk drug substances while FDA develops the list of bulk drug substances that outsourcing facilities can use in compounding under the applicable section of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance finalizes the draft guidance of the same title issued in December 2023 and replaces the final guidance of the same title issued in January 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–3539 for ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B 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 this 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Rechelle Buford, Center for Drug Evaluation and Research, 10903 New Hampshire Ave, Bldg., 51, Silver Spring, MD 20993–0002, 240–402–0447, *compounding@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act'' (2024 503B Interim Policy Guidance). This guidance finalizes the draft guidance entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act'' issued on December 7, 2023 (88 FR 85293), and replaces the guidance of the same title issued in January 2017 (2017 503B Interim Policy Guidance).

Section 503B of the FD&C Act (21 U.S.C. 353b) sets forth the conditions that must be satisfied for human drug products compounded by an outsourcing facility 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 582 (21 U.S.C. 360eee–1) (concerning drug supply chain security requirements). One of the conditions that must be met for a drug product compounded by an outsourcing facility to qualify for these exemptions is that the outsourcing facility does not compound a drug using a bulk drug substance unless: (1) the bulk drug substance appears on a list established by the Secretary of the Department of Health and Human Services identifying bulk drug substances for which there is a clinical need (the 503B bulks list) (see section 503B(a)(2)(A)(i)) or (2) the drug product compounded from such bulk drug substances appears on the drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e) at the time of compounding, distribution, and dispensing (see section 503B(a)(2)(A)(ii) of the FD&C Act).

FDA is developing the 503B bulks list, and this guidance describes FDA's interim policy regarding outsourcing facilities that compound human drug products using bulk drug substances while the list is being developed. This guidance revises the policy described in FDA's 2017 503B Interim Policy Guidance with respect to categorization of certain substances nominated for inclusion on the 503B bulks list. This guidance ends 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 this guidance.

The 2024 503B Interim Policy Guidance describes the conditions under which FDA does not intend to take action against an outsourcing facility for compounding a drug product using certain bulk drug substances that are not eligible for use in compounding under section 503B of the FD&C Act because they do not appear on the 503B bulks list and are not used to compound a drug product that appears on FDA's drug shortage list at the time of compounding, distribution, and dispensing. One of these conditions is that the bulk drug substance appears in Category 1. As described in this guidance, FDA does not intend to categorize bulk drug substances nominated for inclusion on the 503B bulks list on or after the publication date of this guidance. However, FDA intends to consider such substances for inclusion on the 503B bulks list in accordance with the process and clinical need standard established in the FD&C Act (see section 503B(a)(2)(A)(i) of the FD&C Act). FDA is evaluating bulk drug substances nominated for the 503B bulks list on a rolling basis. Substances that appear in Category 1 (including substances nominated with adequate supporting information prior to the date of publication of this guidance) may continue to be within the scope of the policy for Category 1 substances, as described in the guidance, until FDA makes a final determination whether these substances will be placed on the 503B bulks list in accordance with section 503B(a)(2)(A)(i) of the FD&C Act or unless the Agency removes the substances from Category 1 based on, for example, information about safety risks.

Prior to preparing this guidance, FDA considered comments received on the draft guidance. Editorial changes were made to improve clarity, such as updating references to the publication date of this final guidance.

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 the ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B 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

This 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 guidance at either

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 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31545 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–4245]

Study of Sex Differences in the Clinical Evaluation of Medical Products; 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 ''Study of Sex Differences in the Clinical Evaluation of Medical Products.'' Clinical trials and non-interventional studies of medical products should be designed to enroll sufficient numbers of females and males to reflect the prevalence of the disease or condition for which the medical product is being investigated to help ensure the generalizability of results and facilitate exploration of potential differences in effects by sex. This guidance provides recommendations for increasing enrollment of females in clinical trials, analyzing and interpreting sex-specific data, and including sex-specific information in regulatory submissions of medical products. When finalized, this guidance will replace the guidance entitled ''Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs'' issued in July 1993.

DATES: Submit either electronic or written comments on the draft guidance by April 7, 2025 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–2024–D–4245 for ''Study of Sex Differences in the Clinical Evaluation of Medical Products.'' 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; the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; the Office of Policy, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or the Office of Women's Health, 10903 New Hampshire Ave., Bldg. 32, Rm. 2333, Silver Spring, 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: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993–0002, 240–402–8926, *Dat.Doan@fda.hhs.gov;* James Myers, Center for Biologics Evaluation and