Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Action Levels for Lead in Processed Food Intended for Babies and Young Children.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. 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.

In the **Federal Register** of January 25, 2023 (88 FR 4749), we made available a draft guidance for industry entitled ''Action Levels for Lead in Food Intended for Babies and Young Children'' and gave interested parties an opportunity to submit comments by March 27, 2023, for us to consider before beginning work on the final version of the guidance. In the **Federal Register** of April 6, 2023 (88 FR 20525), we announced that we were reopening the comment period until May 8, 2023, to allow interested parties additional time to submit comments. We received several comments on the draft guidance and have modified the final guidance where appropriate. Changes to the guidance include clarifications to the foods that the guidance addresses, including the age range of the foods' intended consumers. We added information about the method that FDA uses to test for lead in food and made several editorial changes to improve clarity of the guidance. We also collected and analyzed additional samples from our Toxic Elements Program and special FDA surveys to inform our exposure and achievability assessments. The guidance announced in this notice finalizes the draft guidance dated January 2023.

In accordance with § 109.6 (21 CFR 109.6), this guidance establishes the following action levels for lead in processed food intended for babies and young children less than 2 years old: 10 parts per billion (ppb) for fruits, vegetables (excluding single-ingredient root vegetables), mixtures (including grain- and meat-based mixtures), yogurts, custards/puddings, and single-ingredient meats; 20 ppb for single-ingredient root vegetables; and 20 ppb for dry infant cereals. Consistent with § 109.6(d), these action levels reflect levels of lead at which FDA may regard the food as adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1)). We intend to consider these action levels, in addition to other factors, when considering whether to bring enforcement action in a particular case.

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 *https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31534 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–2015–D–3517]

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A 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 503A of the Federal Food, Drug, and Cosmetic Act.'' This guidance describes FDA's interim policy concerning compounding by human drug product compounders that are not outsourcing facilities using bulk drug substances 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 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–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 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: Mariestela Buhay, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993–0002, 301–796–7313, *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 503A of the Federal Food, Drug, and Cosmetic Act'' (2024 503A Interim Policy Guidance). This guidance finalizes the draft guidance entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act'' issued on December 7, 2023 (88 FR 85296), and replaces the guidance of the same title issued in January 2017 (2017 503A Interim Policy Guidance).

Section 503A of the FD&C Act (21 U.S.C. 353a) sets forth 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.)

FDA is developing the 503A bulks list, and this guidance describes FDA's interim policy for licensed pharmacists in State-licensed pharmacies and Federal facilities and for licensed physicians who compound human drug products using bulk drug substances while the list is being developed. This guidance revises the policy described in FDA's 2017 503A Interim Policy Guidance with respect to categorization of certain substances nominated for inclusion on the 503A 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 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 of the FD&C Act 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 at § 216.23(a) (21 CFR 216.23(a)). One of these conditions is that the bulk drug substance appears in Category 1. As described in the guidance, FDA does not intend to categorize bulk drug substances nominated for inclusion on the 503A bulks list on or after the publication date of this guidance. However, FDA intends to consider such substances 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 § 216.23(c)). FDA is evaluating bulk drug substances nominated for the 503A 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 that applies to Category 1 substances, as described in this 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.

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 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 ''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

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III. Electronic Access

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Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31546 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–2978]

Food and Drug Administration Animal Food Ingredient Consultation; 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 #294 entitled ''Animal Food Ingredient Consultation (AFIC).'' This guidance describes FDA's interim AFIC process and explains one way FDA will work with firms that are developing animal food ingredients now that the Memorandum of Understanding (MOU) with the Association of American Feed Control Officials (AAFCO) expired on October 1, 2024, and while FDA evaluates the animal Food Additive Petition and Generally Recognized as Safe (GRAS) Notification programs. The AFIC process provides an additional way for engagement with FDA regarding ingredients for which firms may otherwise have used the AAFCO ingredient definition process. AFIC will help FDA identify any potential safety concerns associated with such ingredients. The AFIC process also allows for public awareness of and input on such ingredients. In addition, this guidance describes FDA's enforcement policy for certain ingredients assessed using the AFIC process.

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–2024–D–2978 for ''Animal Food Ingredient Consultation (AFIC).'' 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 guidance to the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section