under the Federal Trade Commission Act and whether the Commission should prescribe new trade regulation rules or other regulatory alternatives to address them. Interested parties have subsequently requested an extension of the public comment period to give them additional time to respond to the ANPR's request for comment.

The Commission agrees that allowing additional time for filing comments in response to the ANPR would help facilitate the creation of a more complete record. The Commission has therefore decided to extend the comment period for 30 days, to February 8, 2023. A 30-day extension will provide commenters adequate time to address the issues raised in the ANPR.

By direction of the Commission.

Joel Christie,

Acting Secretary.

[FR Doc. 2023–01471 Filed 1–24–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 109

[Docket No. FDA–2022–D–0278]

Action Levels for Lead in Food Intended for Babies and Young Children; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance for Industry.'' The draft guidance, when finalized, would establish the following action levels for lead in processed food intended for babies and young children: 10 parts per billion (ppb) for fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats; 20 ppb for root vegetables (single ingredient); and 20 ppb for dry cereals.

DATES: Submit either electronic or written comments on the draft guidance by March 27, 2023 to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance.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–2022–D–0278 for ''Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance for Industry.'' 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.'' We will review this copy, including the claimed confidential information, in our 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 Office of Food Safety, Division of Plant Products and Beverages, Beverages Branch, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Eileen Abt, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1700; or Philip Chao, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance for Industry.'' We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 alternate approach if it satisfies the requirements of the applicable statutes and regulations.

This draft guidance, when finalized, would, in accordance with 21 CFR 109.6, establish the following action levels for lead in food labeled for babies and young children: 10 parts per billion (ppb) for fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats; 20 ppb for root vegetables (single ingredient); and 20 ppb for dry infant cereals. Consistent with 21 CFR 109.6(d), these action levels would 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. We request comments on these proposed action levels in general, including on whether there may be sufficient data or information that would support lower levels for these categories of foods. For example, we request comment on whether there is data or information that show adverse cognitive impacts in children at very low blood levels that could support a lower interim reference level for lead exposure through foods. We are particularly interested in whether there is data and information that would support a lower action level for fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats, given that we estimate that the achievability percentile (*i.e.,* percentage of samples that fall at or below the action level) for this food category would be 90.6 percent if the action level were 5 ppb.

In developing this draft guidance, FDA evaluated data collected for grain-based snacks (*e.g.,* teething biscuits, puffs, rusks, wafers) collected through our Toxic Element Program and FDA surveys (122 samples) and FDA's Total Diet Study (44 samples). Toxic Element Program and FDA survey data showed that the mean lead concentration for these grain-based snacks was 11.1 ppb, with 90th to 95th percentile concentrations of 18.7 to 26.8 ppb. Total Diet Study data had a slightly higher mean lead concentration of 17.6 ppb. We also evaluated baby food consumption data from What We Eat in America, the food consumption portion of the National Health and Nutrition Examination Survey, 2003–2018. These data indicated that consumption of grain-based snacks in this subgroup is relatively low. We request comment about consumption patterns and exposure to lead from this source, as well as any information about the role of these products in the diets of infants and toddlers, to help inform whether an action level for this food category would be appropriate.

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/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: January 19, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–01384 Filed 1–24–23; 8:45 am]

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