TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
530.22(b); Submission(s) of Analytical Method	2	1	2	4,160	8,320

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: July 31, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–17197 Filed 8–5–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1207]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishing and Maintaining a List of U.S. Manufacturers/Processors of Feed Additives, Premixes, Compound Feed, Distillers' Dried Grains, and Distillers' Dried Grains with Solubles for Use with Animals with Interest in Exporting to The People's Republic of China

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 8, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0884. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Establishing and Maintaining a List of U.S. Manufacturers/Processors of Feed Additives, Premixes, Compound Feed, Distillers' Dried Grains, and Distillers' Dried Grains with Solubles for Use with Animals with Interest in Exporting to The People's Republic of China OMB Control Number 0910–0884

This information collection request allows FDA to include respondents who are U.S. manufacturers/processors of feed additives, premixes, compound feed, distillers' dried grains, and distillers' dried grains with solubles (hereinafter, ''manufacturers/processors'' of ''covered products'') on a list of those who wish to export their products to The People's Republic of China (China). On January 15, 2020, the United States and China entered into an Economic and Trade Agreement (the Agreement) which, among other things, will streamline the procedures for, and improve the efficiencies of, the exportation of U.S. covered products to China. These provisions of the Agreement are intended to facilitate trade between the two countries to better meet the demand for U.S. animal feed products in China and to promote the development of animal husbandry in China. Since the timing of the Agreement did not allow for publication of a 60-day notice under the PRA in advance of its implementation, FDA requested and OMB granted emergency review under 5 CFR 1320.13 of a new information collection request.

In the **Federal Register** of April 16, 2020 (85 FR 21242), subsequent to implementation under the emergency clearance, we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Respondents: Manufacturing/processing facilities of covered products interested in exporting animal feed to China.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 1.101(b)(1); Request for list placement to export to China—data elements demonstrating that product meets the foreign purchaser's specifications	450	1	450	0.083	38

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We have revised our burden table. In the 60-day notice published on April 16, 2020, the burden table identified types of respondents. Here we are clarifying that the information being collected is a request from those respondents to be placed on a list. By requesting to be placed on the list, respondents agree to disclose data elements, as agreed upon by the U.S. government and China, that demonstrate the product meets acceptable entry criteria. Since establishing the collection, we have 197 facilities on the list to date. There were fewer emails received, as some of the

companies registered multiple facilities in a single email.

Based on our experience with a similar information collection, upon requesting to be placed on the list, data elements that may be provided to China include the facility name, street address, city, State, and ZIP code of U.S. manufacturers and processors of covered products, who want to be included on the list sent to China.

Manufacturers of these products must currently register with FDA consistent with 21 CFR part 1, subpart H. Therefore, we believe burden associated with this collection should be minimal, but we welcome specific feedback in this regard.

Dated: July 30, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–17161 Filed 8–5–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1099]

Inorganic Arsenic in Rice Cereals for Infants: Action Level; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled ''Inorganic Arsenic in Rice Cereals for Infants: Action Level.'' The guidance identifies for industry an action level for inorganic arsenic in rice cereals for infants that is intended to help protect public health and is achievable with the use of current good manufacturing practices. It also describes our intended sampling and enforcement approach. Thus, the guidance finalizes the approach presented in the draft guidance issued in 2016.

DATES: The announcement of the guidance is published in the **Federal Register** on August 6, 2020.

ADDRESSES: You may submit either electronic or written comments on FDA 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–2016–D–1099 for ''Inorganic Arsenic in Rice Cereals for Infants: Action Level; 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 guidance to Division of Plant Products and Beverages, Office of Food Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–317), 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 guidance.

FOR FURTHER INFORMATION CONTACT: Eileen Abt, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1529.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Inorganic Arsenic in Rice Cereals for Infants: Action Level.'' 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.