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 Thus, the guidance finalizes the approach presented in the draft guidance issued in 2016.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.

In the **Federal Register** of April 6, 2016 (81 FR 19976), we made available a draft guidance for industry entitled ''Inorganic Arsenic in Rice Cereals for Infants: Action Level.'' We also announced the availability of two related scientific documents: a document entitled ''Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants'' (supporting document), and a risk assessment entitled ''Arsenic in Rice and Rice Products Risk Assessment: Report'' (the risk assessment report). We gave interested parties an opportunity to submit comments by July 5, 2016, and later extended the comment period to July 19, 2016 (see 81 FR 42714 (June 30, 2016)).

This guidance finalizes FDA's action level for inorganic arsenic in rice cereals for infants of 100 micrograms per kilogram (µg/kg) or 100 parts per billion (ppb) and identifies FDA's intended sampling and enforcement approach. The basis for the action level is set forth in the revised supporting document. The revised supporting document as well as the risk assessment report originally made available on April 6, 2016 (81 FR 19976), can be accessed at *www.regulations.gov.* The revised supporting document reviews data on inorganic arsenic levels in rice cereals for infants, health effects, and achievability and explains FDA's rationale for identifying an action level of 100 µg/kg for inorganic arsenic in rice cereals for infants.

Arsenic is present in the environment as a naturally occurring substance or as a result of contamination from human activity. In foods, arsenic may be present as inorganic arsenic (the primary toxic form of arsenic) or organic arsenic. Exposure to inorganic arsenic is associated with adverse human health effects including cancer and neurodevelopmental effects. Rice and rice products are common in the American diet, and FDA sampling data have demonstrated that rice and rice products have higher levels of inorganic arsenic than other foods. Furthermore, rice and rice products are a greater potential source of dietary inorganic arsenic exposure for infants and children than for adults, because the dietary patterns of infants and children are often less varied than those of adults, and because infants and children consume more food relative to their body weight than do adults. We expect that that the 100 µg/kg action level, though non-binding, will help protect the public health, by encouraging manufacturers to reduce levels of inorganic arsenic in rice cereals for infants, and we also expect that this level is achievable by industry with the use of current good manufacturing practices. We intend to consider the action level of 100 µg/kg or 100 ppb inorganic arsenic as an important source of information for determining whether infant rice cereal is adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1)).

Comments on the draft guidance requested that we consider establishing action levels for rice-based foods other than infant cereal, lower the action level under 100 ppb, and questioned the achievability of the action level of 100 ppb for inorganic arsenic in infant rice cereals. However, we did not receive new data from the comments supporting establishment of either lower or higher action levels. We determined that we should prioritize efforts to reduce infant exposure to inorganic arsenic from rice because rice intake, primarily through infant rice cereal, is about three times greater for infants than adults in relation to body weight (Ref. 1), and epidemiologic data show that early life exposure to inorganic arsenic, including dietary exposure, can result in a child's decreased performance on certain developmental tests that measure learning (Ref. 1). Thus, the guidance finalizes the approach presented in the draft guidance.

Other comments suggested modifications to the risk assessment report. We note that the risk assessment report underwent extensive interagency review and external peer review before we made it available to the public. None of these comments supported a determination that the risk assessment report needs to be modified. We will continue to monitor research developments on non-cancer adverse health effects, such as neurodevelopmental effects, cardiovascular disease, and diabetes, to determine if new data support changes to the risk assessment report or guidance.

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 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

IV. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA, ''Arsenic in Rice and Rice Products Risk Assessment: Report,'' 2016, *https://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm485278.htm.*

Dated: July 29, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–17169 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–0955]

Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed; Revocation of Approved Method; Correction

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

ACTION: Proposed order; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a proposed order to revoke the approved method for detecting residues of carbadox, a carcinogenic new animal drug used in swine feed. The document was published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Diane Heinz, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5692, *diane.heinz@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 20, 2020, in FR Doc. 2020–15246, on page 43853, the following correction is made:

On page 43853, in the second column, in the header of the document, and also in the third column under *Instructions,* ''Docket No. FDA–2016–N–0832'' is corrected to read ''Docket No. FDA–2020–N–0955''.