In the **Federal Register** of April 6, 2016 (81 FR 19976), we made available a draft guidance for industry entitled ''Inorganic Arsenic in Rice Cereals for Infants: Action Level.''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 The revised supporting document as well as the risk assessment report originally made available on April 6, 2016 (81 FR 19976), can be accessed at *www.regulations.gov.* The revised supporting document reviews data on inorganic arsenic levels in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''.

Dated: August 3, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–17177 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–2018–N–3771]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; 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 the Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is required to report annually on the status of postmarketing requirements (PMRs) and postmarketing commitments (PMCs) required of, or agreed upon by, application holders of approved drug and biological products. The report on the status of the studies and clinical trials that applicants have agreed to, or are required to, conduct is on the FDA's ''Postmarketing Requirements and Commitments: Reports'' web page.

FOR FURTHER INFORMATION CONTACT: Kathy Weil, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5367, Silver Spring, MD 20993–0002, 301–796–0700; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 506B(c) of the FD&C Act (21 U.S.C. 356b(c)) requires FDA to publish an annual report on the status of postmarketing studies that applicants have committed to, or are required to conduct, and for which annual status reports have been submitted.

Under §§ 314.81(b)(2)(vii) and 601.70 (21 CFR 314.81(b)(2)(vii) and 601.70), applicants of approved drugs and licensed biologics are required to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study or clinical trial either required by FDA (PMRs) or that they have committed to conduct (PMCs), either at the time of approval or after approval of their new drug application, abbreviated new drug application, or biologics license application. The status of PMCs concerning chemistry, manufacturing, and production controls and the status of other studies or clinical trials conducted on an applicant's own initiative are not required to be reported under §§ 314.81(b)(2)(vii) and 601.70 and are not addressed in this report. Furthermore, section 505(o)(3)(E) of the FD&C Act (21 U.S.C. 355(o)(3)(E)) requires that applicants report periodically on the status of each required study or clinical trial and each study or clinical trial ''otherwise undertaken . . . to investigate a safety issue . . . . ''

An applicant must report on the progress of the PMR/PMC on the anniversary of the drug product's approval [1] until the PMR/PMC is completed or terminated and FDA determines that the PMR/PMC has been fulfilled or that the PMR/PMC is either no longer feasible or would no longer provide useful information.

II. Fiscal Year 2019 Report

With this notice, FDA is announcing the availability of the Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' Information in this report covers any PMR/PMC that was established, in writing, at the time of approval or after approval of an application or a supplement to an application and summarizes the status of PMRs/PMCs in fiscal year (FY) 2019 (*i.e.,* as of September 30, 2019). Information summarized in the report reflects combined data from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research and includes the following: (1) The number of applicants with open PMRs/PMCs; (2) the number of open PMRs/PMCs; (3) the timeliness of applicant submission of the annual status reports (ASRs); (4) FDA-verified status of open PMRs/PMCs reported in § 314.81(b)(2)(vii) or § 601.70 ASRs; (5) the status of closed PMRs/PMCs; and (6) the distribution of the status by fiscal year of establishment [2] (FY2013 to FY2019) for PMRs and PMCs open at the end of FY2019, or those closed within FY2019. Additional information about PMRs/PMCs is provided on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarket-requirements-and-commitments.*

[1] An applicant must submit an annual status report on the progress of each open PMR/PMC within 60 days of the anniversary date of U.S. approval of the original application or on an alternate reporting date that was granted by FDA in writing. Some applicants have requested and been granted by FDA alternate annual reporting dates to facilitate harmonized reporting across multiple applications.

Dated: July 31, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–17113 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–2018–D–2032]

Limited Population Pathway for Antibacterial and Antifungal Drugs; 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 ''Limited Population Pathway for Antibacterial and Antifungal Drugs.'' This guidance provides information on the implementation of the limited population pathway provision of the 21st Century Cures Act (Cures Act), which established the limited population pathway for antibacterial and antifungal drugs (LPAD pathway). This guidance finalizes the draft guidance of the same name issued on June 13, 2018.

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 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

[2] The establishment date is the date of the formal FDA communication to the applicant that included the final FDA-required (PMR) or requested (PMC) postmarketing study or clinical trial.