The reporting and third-party disclosure burden estimates are based on FDA's records, which show that there are six manufacturers of infant formula and that there have been, on average, two infant formula recalls per year for the past 3 years. Based on this information, we estimate that there are, on average, approximately two infant formula recalls per year.

Thus, we estimate that two respondents conduct recalls annually pursuant to §§ 107.230, 107.240, and 107.250. The estimated number of respondents for § 107.260 is minimal because we seldom use this section; therefore, we estimate that there are one or fewer respondents annually for § 107.260. The estimated number of hours per response is an average based on our experience and information from firms that have conducted recalls. FDA estimates that two respondents will conduct infant formula recalls under § 107.230 and that it takes a respondent 4,450 hours to comply with the requirements of that section, for a total of 8,900 hours. FDA estimates that two respondents conduct infant formula recalls under § 107.240 and that it takes a respondent 1,482 hours to comply with the requirements of that section, for a total of 2,964 hours. FDA estimates that two respondents submit recommendations for termination of infant formula recalls under § 107.250 and that it takes a respondent 120 hours to comply with the requirements of that section, for a total of 240 hours. Finally, FDA estimates that one respondent needs to carry out additional effectiveness checks and issue additional notifications, for a total of 625 hours. Therefore, the total annual burden hours for reporting is 12,729 hours (8,900 + 2,964 + 240 + 625).

Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
107.230; Elements of infant formula recall	2	1	2	50	100
107.260; Revision of an infant formula recall	1	1	1	25	25
Total					125

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

Table 2 reports FDA's third-party disclosure burden estimates for §§ 107.230 and 107.260. The estimated burden hours per disclosure is an average based on FDA's experience. The third-party disclosure burden in § 107.230 is the requirement to promptly notify each affected direct account (customer) about the recall, and if the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post a notice of the recall at the point of purchase. FDA estimates that two respondents conduct infant formula recalls under § 107.230 and that it takes a respondent 50 hours to comply with the third-party disclosure requirements of that section, for a total of 100 hours. The third-party disclosure burden in § 107.260 is the requirement to issue additional notifications where the recall strategy or implementation is determined to be deficient. FDA estimates that one respondent issues additional notifications under § 107.260 and that it takes a respondent 25 hours to comply with the third-party disclosure requirements of that section, for a total of 25 hours. The total annual third-party disclosure burden is 125 hours (100 + 25).

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: April 20, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–08894 Filed 4–24–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5664]

Standardized Medicated Feed Assay Limits; Draft Guidance for Industry; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is extending the comment period for the notice of availability that published in the **Federal Register** on February 27, 2020. In that notice, FDA requested comments on the draft guidance for industry (GFI) #264 entitled ''Standardized Medicated Feed Assay Limits.'' The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the document published February 27, 2020 (85 FR 11369). Submit either electronic or written comments on the draft guidance by June 26, 2020, to ensure that the Agency considers your comments on this draft guidance before it begins 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–2019–D–5664 for ''Standardized Medicated Feed Assay Limits.'' 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.

• 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.

FOR FURTHER INFORMATION CONTACT: Katie Ciesienski, Center for Veterinary Medicine (HFV–141), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0676, *Katie.Ciesienski@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 27, 2020, FDA published a notice announcing the availability of draft GFI #264 entitled ''Standardized Medicated Feed Assay Limits'' with a 60-day comment period. This draft guidance recommends a standardized set of assay limits for medicated feeds. Standardized medicated feed assay limits allow predictability in the review process as the sponsor can determine early in the drug development process what assay limits they should expect to meet for medicated feeds used in Target Animal Safety, Effectiveness, Chemistry, Manufacturing, and Controls, Bioequivalence, and Human Food Safety residue chemistry studies. Assay limits are used pre-approval to ensure that medicated feeds in these studies contain the appropriate amount of drug, and post-approval for compliance and customer service purposes.

The Agency has received a request for a 90-day extension of the comment period. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a comprehensive response.

FDA has considered the request and is extending the comment period for the notice of availability for 60 days, until June 26, 2020. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments.

Dated: April 21, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–08890 Filed 4–24–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Secretary's Advisory Commission on Childhood Vaccines (ACCV) has scheduled a public meeting. Information about ACCV and the agenda for this meeting can be found on the ACCV website at *https://www.hrsa.gov/advisory-committees/vaccines.*

DATES: May 18, 2020. This meeting will begin at 9:00 a.m. ET.

ADDRESSES: This meeting will be held by Adobe Connect webinar and teleconference.

• *Webinar link: https://hrsa.connectsolutions.com/accv/.*

• *Conference call-in number:* 888–790–1734, passcode: 4177683.

FOR FURTHER INFORMATION CONTACT: Annie Herzog, Division of Injury Compensation Programs, HRSA, 5600 Fishers Lane, 08N186B, Rockville, Maryland 20857; 301–443–6634; or *aherzog@HRSA.gov.*

SUPPLEMENTARY INFORMATION: The ACCV provides advice and recommendations to the Secretary of HHS on policy, program development, and other issues related to implementation of the National Vaccine Injury Compensation Program (VICP) and concerning other matters as described under section 2119 of the Public Health Service Act (42 U.S.C. 300aa–19).

During the May 18, 2020, meeting, the ACCV will discuss a draft VICP Notice of Proposed Rulemaking. Agenda items are subject to change as priorities dictate. Refer to the ACCV website for any updated information concerning the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested