technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Sec. 806 [42 U.S.C. 2991d–1](a)(1) and Sec. 811 [42 U.S.C. 2992].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–12739 Filed 6–11–20; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4533]

Compounding Animal Drugs From Bulk Drug Substances; Draft Guidance for Industry; Availability; Extension of Comment Period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 the Agency) is extending the comment period for the notice of availability that published in the **Federal Register** on November 20, 2019. In that notice, FDA requested comments on the draft guidance for industry (GFI) #256 entitled ''Compounding Animal Drugs from Bulk Drug Substances.'' FDA is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is further extending the comment period on the document published November 20, 2019 (84 FR 64085), which was reopened in a document published February 20, 2020 (85 FR 9783). Submit either electronic or written comments on the draft guidance by October 15, 2020, to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance.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–2018–D–4533 for ''Compounding Animal Drugs From Bulk Drug Substances.'' 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.'' 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Eric Nelson, Division of Compliance (HFV–230), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–7001, *cvmcompliance@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 20, 2019, FDA published a notice announcing the availability of draft GFI #256 entitled ''Compounding Animal Drugs From Bulk Drug Substances'' with a 90-day comment period. We requested comments on the draft guidance with respect to animal drug compounding from bulk drug substances under certain circumstances when no other medically appropriate treatment option exists.

Interested persons were originally given until February 18, 2020, to comment on the draft guidance. The Agency received requests to allow interested persons additional time to comment. The requests conveyed concern that the initial 90-day comment period did not allow sufficient time to develop a comprehensive response. FDA considered these requests and reopened the comment period for an additional 120 days, until June 17, 2020 (85 FR 9783).

Since then, FDA has received additional requests to further extend the comment period. FDA has considered the requests and is extending the comment period for the notice of availability for another 120 days, until October 15, 2020. The Agency believes that a further extension of 120 days allows adequate time for interested persons to submit comments.

Dated: June 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–12750 Filed 6–11–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0144]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Qualified Importer Program

AGENCY: Food and Drug Administration, 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 July 13, 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 0910–0840. 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.

Agency Information Collection Activities; Proposed Collection; Comment Request; FDA's Voluntary Qualified Importer Program

OMB Control Number 0910–0840—Extension

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production. Under FSMA, those that import food have a responsibility to ensure that their suppliers produce food that meets U.S. safety standards.

FSMA also requires FDA to establish a voluntary, fee-based program for the expedited review and importation of foods by importers who achieve and maintain a high level of control over the safety and security of their supply chains. This control includes importation of food from facilities that have been certified under FDA's accredited third-party certification program, as well as other measures that support a high level of confidence in the safety and security of the food they import. Expedited entry incentivizes importers to adopt a robust system of supply chain management and further benefits public health by allowing FDA to focus its resources on food entries that pose a higher risk to public health.

Section 302 of FSMA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding new section 806, Voluntary Qualified Importer Program (VQIP) (21 U.S.C. 384b). Section 806(a)(1) of the FD&C Act directs FDA to establish this voluntary program for the expedited review and importation of food, and to establish a process for the issuance of a facility certification to accompany food offered for importation by importers participating in VQIP. Section 806(a)(2) directs FDA to issue a guidance document related to participation in, revocation of such participation in, reinstatement in, and compliance with VQIP. Accordingly, in the **Federal Register** of November 14, 2016 (81 FR 79502), FDA published a notice announcing the availability of a final guidance for industry entitled ''FDA's Voluntary Qualified Importer Program.'' The guidance is available from our website at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-fdas-voluntary-qualified-importer-program.*

In the **Federal Register** of February 5, 2020 (85 FR 6556) we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. We estimate the burden of the information collection as follows:

TABLE 1—ONE-TIME RECORDKEEPING BURDEN [1]

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Quality Assurance Program (QAP) preparation	200	1	200	160	32,000

[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 one-time recordkeeping burden estimate. On average, the preparation of a QAP by a VQIP applicant is estimated at approximately 160 hours (110 + 40 + 10). In estimation of the one-time recordkeeping burden to prepare a QAP manual, we assume that VQIP importers do not already have a similar manual in place (*e.g.,* food safety plan under the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food regulation (21 CFR part 117); food defense plan under the Focused Mitigation Strategies to Protect Food Against Intentional Adulteration regulation (IA regulation) (21 CFR part 121)). We continue to use the recordkeeping burden of preparing a food safety plan under part 117, 110 hours, as a proxy for the burden to prepare QAP Food Safety Policies and Procedures. We continue to estimate that, on average, it would take 40 hours for an applicant to prepare the food defense portion of the VQIP QAP, similar to the estimated burden for preparing a food defense plan under the IA regulation. We also continue to