submission to CFSAN. The following questions are covered in this guidance: (1) What types of industry-initiated actions are subject to a claim of categorical exclusion? (2) What must a claim of categorical exclusion include by regulation? (3) What is an EA? (4) When is an EA required by regulation and what format should be used? (5) What are extraordinary circumstances? and (6) What suggestions does CFSAN have for preparing an EA? Although CFSAN encourages industry to use the EA formats described in the guidance because standardized documentation submitted by industry increases the efficiency of the review process, alternative approaches may be used if these approaches satisfy the requirements of the applicable statutes and regulations. We are requesting the extension of OMB approval for the information collection provisions in the guidance.

Description of Respondents: The likely respondents include businesses engaged in the manufacture or sale of food, food ingredients, and substances used in materials that come into contact with food.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15 (a) & (d) (to cover CE's under 25.32(i))	47	1	47	8	376
25.15 (a) & (d) (to cover CE's under 25.32(o))	1	1	1	8	8
25.15 (a) & (d) (to cover CE's under 25.32(q))	3	1	3	8	24
25.40 (a) & (c) EA's	57	1	57	180	10,260
Total					10,668

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

The estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for categorical exclusions listed under § 25.32(i) and (q) that the Agency has received in the past 3 years. Please note that, in the past 3 years, there have been no submissions that requested an action that would have been subject to the categorical exclusion in § 25.32(o). To avoid counting this burden as zero, we have estimated the burden for this categorical exclusion at one respondent making one submission a year for a total of one annual submission. The burden for submitting a categorical exclusion is captured under § 25.15(a) and (c).

To calculate the estimate for the hours per response values, we assumed that the information requested in this guidance for each of these three categorical exclusions is readily available to the submitter. For the information requested for the exclusion in § 25.32(i), we expect that submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for attachment to the claim for categorical exclusion. We believe that this effort should take no longer than 8 hours per submission. For the information requested for the categorical exclusions in § 25.32(o) and (q), the submitters will almost always merely need to copy existing documentation and attach it to the claim for categorical exclusion. We believe that collecting this information should also take no longer than 8 hours per submission.

For the information requested for the environmental assessments in § 25.40(a) and (c), we believe that submitters will submit an average of 57 environmental assessments annually. We estimate that each submitter will prepare an EA within 3 weeks (120 hours) and revise the EA based on Agency comments (between 40 to 60 hours), for a total preparation time of 180 hours. The burden relating to this collection has been previously approved under OMB control number 0910–0322, ''Environmental Impact Consideration—21 CFR part 25''. Upon approval of this collection of information by OMB, FDA will revise OMB control number 0910–0322 to remove the annual reporting burden for categorical exclusions and environmental assessment requests related to food additive petitions, color additive petitions, requests from exemption from regulation as a food additive, and submission of a food contact notification for a food contact substance. The future burden for categorical exclusion or environmental assessments for these requests will be captured under OMB control number 0910–0541, this collection of information.

Dated: August 19, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2016–20369 Filed 8–24–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1229]

Current Good Manufacturing Practice Requirements for Food for Animals; Draft 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 draft guidance for industry #235 entitled ''Current Good Manufacturing Practice Requirements for Food for Animals.'' This draft guidance helps domestic and foreign facilities that are required to register as food facilities under the Federal Food, Drug, and Cosmetic Act (FD&C Act) determine whether and how they need to comply with the current good manufacturing practice requirements of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals final rule.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 23, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–1229 for ''Current Good Manufacturing Practice Requirements for Food for Animals.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jeanette Murphy, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240–402–6246, *jenny.murphy@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #235 entitled ''Current Good Manufacturing Practice Requirements for Food for Animals.'' This draft guidance is intended for domestic and foreign facilities that are required to register as food facilities under the FD&C Act because they manufacture, process, pack, or hold animal food for consumption in the United States.

This draft guidance contains information to help these facilities determine whether they need to comply with the current good manufacturing practice (CGMP) requirements for animal food established in the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals final rule published on September 17, 2015. (80 FR 56170). The CGMP requirements are codified in 21 CFR part 507, subpart B, and related requirements are codified in 21 CFR part 507, subpart A. The draft guidance additionally provides recommendations for compliance with the CGMP requirements for animal food, training, and recordkeeping.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on CGMP requirements for food for animals. 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.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 507 have been approved under OMB control number 0910–0789.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: August 19, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2016–20300 Filed 8–24–16; 8:45 am]

BILLING CODE 4164–01–P