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**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 this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1670, Silver Spring, MD 20993-0002, 240-402-7930.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a guidance for industry entitled "Abbreviated New Drug Application Submissions—Refuse to Receive for Lack of Justification of Impurity

Limits." This guidance is intended to assist applicants preparing to submit to FDA ANDAs and prior approval supplements to ANDAs for which the applicant is seeking approval of a new strength of the drug product. The guidance highlights serious deficiencies in impurity information that may cause FDA to RTR an ANDA. Specifically, these deficiencies include: (1) Failing to provide justification for proposed limits for specified identified impurities in drug substances and drug products that are above qualification thresholds; (2) failing to provide justification for specified unidentified impurities that are above identification thresholds; and (3) proposing limits for unspecified impurities (e.g., any unknown impurity) that are above identification thresholds.

FDA evaluates each submitted ANDA individually to determine whether it is sufficiently complete to permit a substantive review and thus can be received by FDA. The Agency cannot receive an ANDA unless it contains the information required under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) and related regulations (e.g., 21 CFR 314.101(b)(1)). FDA issued the guidance for industry "Abbreviated New Drug Application Submissions—Refuse to Receive Standards" to explain in some detail the kind of omissions that can lead to a RTR determination. A draft of this guidance was published on September 17, 2014, with the title "ANDA Submissions—Refuse to Receive for Lack of Proper Justification of Impurity Limits." Upon review of the comments submitted to the draft guidance, FDA removed the word "proper" from the title to emphasize that this guidance does not apply to the technical review of impurity limit justifications submitted in an ANDA.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Abbreviated New Drug Application Submissions—Refuse to Receive for Lack of Justification of Impurity Limits." 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.

##### **II. Electronic Access**

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: August 22, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-20399 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-2013-N-1147]

#### **Agency Information Collection Activities; Proposed Collection; Comment Request; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our guidance document entitled "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition."

**DATES:** Submit either electronic or written comments on the collection of information by October 24, 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-2013-N-1147 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition.” 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.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and

assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition—OMB Control Number 0910-0541—Extension

As an integral part of its decision making process, we are obligated under the National Environmental Policy Act of 1969 (NEPA) to consider the environmental impact of our actions, including allowing notifications for food contact substances to become effective and approving food additive petitions, color additive petitions, GRAS affirmation petitions, requests for exemption from regulation as a food additive, and actions on certain food labeling citizen petitions, nutrient content claims petitions, and health claims petitions. In 1997, we amended our regulations in part 25 (21 CFR part 25) to provide for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant effect on the human environment (62 FR 40570, July 29, 1997). As a result of that rulemaking, we no longer routinely require submission of information about the manufacturing and production of our regulated articles. We also have eliminated the previously required Environmental Assessment (EA) and abbreviated EA formats from the amended regulations. Instead, we have provided guidance that contains sample formats to help industry submit a claim of categorical exclusion or an EA to the Center for Food Safety and Applied Nutrition (CFSAN). The guidance document entitled “Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition” identifies, interprets, and clarifies existing requirements imposed by statute and regulation, consistent with the Council on Environmental Quality regulations (40 CFR 1507.3). It consists of recommendations that do not themselves create requirements; rather, they are explanatory guidance for our own procedures in order to ensure full compliance with the purposes and provisions of NEPA.

The guidance provides information to assist in the preparation of claims of categorical exclusion and EAs for

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 <sup>1</sup>

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

<sup>1</sup> 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.

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**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.