

the Currency, the Office of Thrift Supervision, the Federal Deposit Insurance Corporation, and the National Credit Union Administration. There has been no consultation outside of the Federal Reserve System with regard to the current proposal to extend the FR 4198 for three years, with revision.

Board of Governors of the Federal Reserve System, June 20, 2019.

**Michele Taylor Fennell,**

*Assistant Secretary of the Board.*

[FR Doc. 2019-13490 Filed 6-24-19; 8:45 am]

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## 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 Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 August 26, 2019.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 26, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 26, 2019. Comments received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### 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-2013-N-1147 for "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition." Received comments, those filed in a timely manner (see **ADDRESSES**), 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.gpo.gov/fdsys/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:** 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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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, generally recognized as safe (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. We have provided guidance that contains sample formats to help industry submit a claim of categorical exclusion or an Environmental Assessment (EA) to the Center for Food Safety and Applied Nutrition (CFSAN). The 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.

*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 part environmental impact considerations	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
<b>Total</b> .....					<b>10,668</b>

<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 (CE) listed under § 25.32(i) and (q) that we have received in the past 3 years. To avoid counting the burden attributed to § 25.32(o) 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.

Based on a current review of the information collection, we have made no adjustments to the currently approved estimate.

Dated: June 19, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019-13434 Filed 6-24-19; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-N-0482]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting Associated With New Animal Drug Applications and Veterinary Master Files

**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:** Fax written comments on the collection of information by July 25, 2019.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0032. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, [PRStaff@fda.hhs.gov](mailto:PRStaff@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.

#### Reporting Associated With New Animal Drug Applications (NADA) and Veterinary Master Files—21 CFR 514.1, 514.4, 514.5, 514.6, 514.8, 514.11, and 558.5

*OMB Control Number 0910-0032—Extension*

Under section 512(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(b)(1)), any person may file a new animal drug application (NADA) seeking our approval to legally market a new animal drug. Section 512(b)(1) of the FD&C Act sets forth the information required to be submitted in a NADA. Sections 514.1, 514.4, 514.6, 514.8, and 514.11 of our regulations (21 CFR 514.1, 514.4, 514.6, 514.8, and 514.11) further specify the information that the NADA must contain. The application must include safety and effectiveness data, proposed labeling, product manufacturing information, and where necessary, complete information on food safety (including microbial food safety) and any methods used to determine residues of drug chemicals in edible tissue from food producing animals. FDA Guidance for Industry #152 outlines a risk assessment approach for evaluating the microbial food safety of antimicrobial new animal drugs. We request that applicants utilize Form FDA 356V, as appropriate, to ensure efficient and accurate processing of information to support new animal drug approval.

Under section 512(b)(3) of the FD&C Act, any person intending to file a NADA or supplemental NADA or a request for an investigational exemption under section 512(j) of the FD&C Act is entitled to one or more conferences with us prior to making a submission. Section 514.5 of our regulations (21 CFR 514.5) describes the procedures for requesting, conducting, and documenting presubmission conferences. We have found that these meetings have increased the efficiency of the drug development and drug review processes. We encourage sponsors to submit data for review at the most appropriate and productive times in the drug development process. Rather than submitting all data for review as part of a complete application, we have found that the submission of data supporting discrete technical sections during the investigational phase of the new animal drug is the most appropriate and productive. This “phased review” of data submissions has created efficiencies for both us and the animal pharmaceutical industry.

Additionally, we have found that various uses of veterinary master files have increased the efficiency of the drug

development and drug review processes for both us and the animal pharmaceutical industry. A veterinary master file is a repository for submission to FDA’s Center for Veterinary Medicine of confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more veterinary drugs. The benefits of veterinary master files include confidential exchange of information with FDA, a process for reporting information outside of a NADA or an investigational new animal drug (INAD) file, as well as an opportunity for increased communication with FDA during early stages of product development. Respondents may choose to use veterinary master files to provide and organize confidential detailed information to the Agency. A holder of a veterinary master file may also authorize other parties to reference information in the veterinary master file without disclosing information in the file to those parties. Veterinary master files can be used as repositories for information that can be referenced in multiple submissions to the Agency, thus minimizing paperwork burden. Veterinary master files are already used by the animal pharmaceutical industry in support of information being submitted for NADAs, abbreviated new animal drug applications (ANADAs), INAD files, and generic investigational new animal drug (JINAD) files. In previous information collection requests, we have included the time necessary to compile and submit such information to veterinary master files within the burden estimates provided for applications and amended applications (for NADAs and INAD files) and abbreviated applications and amended abbreviated applications (for ANADAs and JINAD files), respectively. We are now combining the time necessary to compile and submit such information to veterinary master files within the burden estimates provided in this collection of information.

We are also developing new approaches to permit more complex uses of veterinary master files to facilitate the development of animal drug products. We expect respondents will want to use veterinary master files to submit information to us for review and consultation during all phases of animal drug product development (including product development that precedes the establishment of an INAD file or the submission of a NADA). This information could include information about processes, facilities, or articles used in the manufacturing, processing,