

[www.reginfo.gov/public/do/PRAMain](http://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 0910–0133. 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](mailto: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.

**Temporary Marketing Permit Applications—21 CFR 130.17(c) and (i)**

*OMB Control Number 0910–0133—Extension*

Section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341) (FD&C Act) directs FDA to issue regulations establishing definitions and standards of identity for food. Under section 403(g) of the FD&C Act (21 U.S.C. 343(g)), a food that is subject to a definition and standard of identity prescribed by regulation is misbranded if it does not conform to such definition and standard of identity. Section 130.17 (21 CFR 130.17) provides for the issuance by FDA of temporary marketing permits that enable the food industry to test consumer acceptance and measure the technological and commercial feasibility in interstate commerce of experimental packs of food that deviate from applicable definitions and standards of identity. Section 130.17(c) enables the Agency to monitor the manufacture, labeling, and distribution of experimental packs of food that deviate

from applicable definitions and standards of identity. The information so obtained can be used in support of a petition to establish or amend the applicable definition or standard of identity to provide for the variations. Section 130.17(i) specifies the information that a firm must submit to FDA to obtain an extension of a temporary marketing permit.

*Description of Respondents:*

Respondents to this collection of information include private sector businesses including institutional and/or industrial customers and food industry members such as manufacturers, packers, or distributors desiring to apply for a temporary marketing permit or permit extension.

In the **Federal Register** of April 16, 2020 (85 FR 21247), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
130.17(c); Request for temporary marketing permit .....	13	2	26	25	650
130.17(i); Request to extend marketing permit .....	1	2	2	2	4
Total .....					654

<sup>1</sup> 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 burden estimate.

Dated: July 31, 2020.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2020–17168 Filed 8–5–20; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2008–N–0312]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Extralabel Drug Use in Animals**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, 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 (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 reporting requirements associated with extralabel drug use in animals.

**DATES:** Submit either electronic or written comments on the collection of information by October 5, 2020.

**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 October 5, 2020. The <https://www.regulations.gov>

electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 5, 2020. 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-2008-N-0312 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Extralabel Drug Use in Animals.” 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, 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:**

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, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3521), 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.

#### **Extralabel Drug Use for Animals—21 CFR 530**

*OMB Control Number 0910-0325—Extension*

The Animal Medicinal Drug Use Clarification Act of 1994 (Pub. L. 103-396) allows a veterinarian to prescribe the extralabel use of approved new animal drugs. Also, it permits FDA, if it finds that there is a reasonable probability that the extralabel use of an animal drug may prevent the risk to the public health, to establish a safe level for a residue from the extralabel use of the drug, and to require the development of an analytical method for the detection of residues above that established safe level (21 CFR 530.22(b)). Although to date, we have not established a safe level for a residue from the extralabel use of any new animal drug and, therefore, have not required the development of analytical methodology, we believe that there may be instances when analytical methodology will be required. We are, therefore, estimating the reporting burden based on two methods being required annually. The requirement to establish an analytical method may be fulfilled by any interested person. We believe that the sponsor of the drug will be willing to develop the method in most cases. Alternatively, FDA, the sponsor, and perhaps a third party may cooperatively arrange for method development. The respondents may be sponsors of new animal drugs; State, Federal, and/or State Agencies; academia; or individuals.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR Part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
530.22(b); Submission(s) of Analytical Method .....	2	1	2	4,160	8,320

<sup>1</sup> 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 burden estimate.

Dated: July 31, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–17197 Filed 8–5–20; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2020–N–1207]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishing and Maintaining a List of U.S. Manufacturers/Processors of Feed Additives, Premixes, Compound Feed, Distillers' Dried Grains, and Distillers' Dried Grains with Solubles for Use with Animals with Interest in Exporting to The People's Republic of China**

**AGENCY:** Food and Drug Administration, Health and Human Services (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 September 8, 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 0910–0884. 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](mailto: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.

**Establishing and Maintaining a List of U.S. Manufacturers/Processors of Feed Additives, Premixes, Compound Feed, Distillers' Dried Grains, and Distillers' Dried Grains with Solubles for Use with Animals with Interest in Exporting to The People's Republic of China OMB Control Number 0910–0884**

This information collection request allows FDA to include respondents who

are U.S. manufacturers/processors of feed additives, premixes, compound feed, distillers' dried grains, and distillers' dried grains with solubles (hereinafter, “manufacturers/processors” of “covered products”) on a list of those who wish to export their products to The People's Republic of China (China). On January 15, 2020, the United States and China entered into an Economic and Trade Agreement (the Agreement) which, among other things, will streamline the procedures for, and improve the efficiencies of, the exportation of U.S. covered products to China. These provisions of the Agreement are intended to facilitate trade between the two countries to better meet the demand for U.S. animal feed products in China and to promote the development of animal husbandry in China. Since the timing of the Agreement did not allow for publication of a 60-day notice under the PRA in advance of its implementation, FDA requested and OMB granted emergency review under 5 CFR 1320.13 of a new information collection request.

In the **Federal Register** of April 16, 2020 (85 FR 21242), subsequent to implementation under the emergency clearance, we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

**Respondents:** Manufacturing/processing facilities of covered products interested in exporting animal feed to China.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR Section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 1.101(b)(1); Request for list placement to export to China—data elements demonstrating that product meets the foreign purchaser's specifications .....	450	1	450	0.083	38

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

We have revised our burden table. In the 60-day notice published on April 16, 2020, the burden table identified types of respondents. Here we are clarifying that the information being collected is a

request from those respondents to be placed on a list. By requesting to be placed on the list, respondents agree to disclose data elements, as agreed upon by the U.S. government and China, that

demonstrate the product meets acceptable entry criteria. Since establishing the collection, we have 197 facilities on the list to date. There were fewer emails received, as some of the