compile and submit the readily available pediatric use information required under section 515A(a) of the FD&C Act. Respondents are permitted to submit information relating to uses of the device outside the approved or proposed indication if such uses are described or acknowledged in acceptable sources of readily available information. We estimate that 20 percent of respondents submitting information required by section 515A(a) of the FD&C Act will choose to submit this information and that it will take 30 minutes for them to do so.

In the **Federal Register** of December 2, 2019 (84 FR 65986), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity/21 CFR part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pediatric information in an original PMA or PDP—814.20(b)(13).	11	1	11	8	88
Pediatric information in a PMA amendment—814.37(b)(2).	5	1	5	8	40
Pediatric information in a PMA supplement—814.39(c)(2)(i).	928	1	928	2	1,856
Pediatric information in an HDE—814.104(b)(6)	1	1	1	8	8
Pediatric information for uses outside approved indication.	800	1	800	.5 (30 minutes)	400
Total					2,392

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

Our estimated burden and corresponding responses reflect the requirements under section 515A(a) of the FD&C Act, in addition to the submission of data related to pediatric uses outside an approved indication, as described in the document entitled ''Providing Information About Pediatric Uses of Medical Devices—Guidance for Industry and Food and Drug Administration Staff.'' OMB previously approved the information collection related to uses outside an approved indication under OMB control number 0910–0762. As the information collection uses the same data and relies upon the same legal authority as OMB control number 0910–0748, we intend to discontinue OMB control number 0910–0762 and consolidate the information collection accordingly. Our estimated burden for the information collection reflects an overall increase of 632 hours. Additionally, we have altered the title of the collection to reflect all collections of pediatric uses.

Our estimated burden for the information collection reflects an overall increase of 632 hours and a corresponding increase of supplements and of uses outside of approved indications. We attribute this adjustment to an increase in the number of supplements we received over the last 5 years and merging data from discontinued OMB control number 0910–0762.

Dated: April 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–08010 Filed 4–15–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1207]

Agency Information Collection Activities; Proposed Collection; 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, 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with establishing and maintaining a list of U.S. manufacturers and processors interested in exporting to the People's Republic of China.

DATES: Submit either electronic or written comments on the collection of information by June 15, 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 June 15, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 15, 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–2020–N–1207 for ''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.'' 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.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.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

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—Extension

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 the Office of Management and Budget (OMB) granted emergency review under 5 CFR 1320.13 of a new information collection request. Accordingly, we are now inviting comment on the estimated burden we associate with the proposed information collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
U.S. manufacturers/processors of covered products	450	1	450	0.083	38

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

This information collection gathers the facility name, street address, city, state, and zip code of U.S. manufacturers and processors of covered products, who want to be included on the list sent to China. Because similar information is currently maintained by respondents in conjunction with registration, we believe burden associated with this collection to be minimal. However, as a new information collection, we invite comment specifically in this regard. This is a new information collection. Our estimate is based on our experience with similar information collection.

Dated: April 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–08007 Filed 4–15–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0804]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification Procedures

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 May 18, 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 0910–0120. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Premarket Notification Procedures—21 CFR Part 807, Subpart E

OMB Control Number 0910–0120—Revision

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(k)) and implementing regulations in part 807 (21 CFR part 807, subpart E) require a premarket notification submission (''510(k)'') at least 90 days before the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. Based on the information provided in the notification, FDA determines whether the new device is substantially equivalent to a legally marketed device, as defined in § 807.92(a)(3). If the device is determined to be not substantially equivalent to a legally marketed device, it must have an approved premarket approval application (PMA), product development protocol, humanitarian device exemption (HDE), request for an evaluation of automatic class III designation (De Novo request), or be reclassified into class I or class II before being marketed (see OMB control numbers 0910–0231, 0910–0332, 0910–0844, and 0910–0138). FDA makes the final decision of whether a device is substantially equivalent or not substantially equivalent.

Section 807.81 governs when a 510(k) is required. A 510(k) is required to be submitted by a person who is: (1) Introducing a device to the market for the first time; (2) introducing a device into commercial distribution for the first time by a person who is required to register; or (3) introducing or reintroducing a device that is significantly changed or modified in design, components, method of manufacturer, or the intended use that could affect the safety and effectiveness of the device. Section 807.87 lists the information required in each 510(k).

Form FDA 3514, a summary cover sheet form, assists respondents in categorizing administrative 510(k) information for submission to FDA. This form also assists respondents in categorizing information for other FDA medical device programs such as PMAs, investigational device exemptions, De Novo requests, HDEs, etc.

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amended section 514 of the FD&C Act (21 U.S.C. 360d). Amended section 514 of the FD&C Act allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions including 510(k) or other requirements. FDA has published and updated regularly the list of recognized standards since enactment of FDAMA and has allowed 510(k) submitters to certify conformance to recognized standards to meet the requirements of § 807.87.

Under § 807.90(a)(3), inquiries regarding a 510(k) submission should be in writing and sent to one of the addresses in § 807.90(a).

Under § 807.87(h), each 510(k) submitter must include in the 510(k) either a summary of the information in the 510(k) as required by § 807.92 (510(k) summary) or a statement certifying that the submitter will make available upon request the information in the 510(k) with certain exceptions as per § 807.93 (510(k) statement).

Section 745A(b) of the FD&C Act (21 U.S.C. 379k–1(b), amended by section 207 of the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52), requires that submissions for devices under section 510(k), among other submission types, be submitted in electronic format specified by FDA. In addition, in the Medical Device User