ANNUAL BURDEN ESTIMATES—Continued

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden minutes per response	Annual burden minutes
Emergency Significant Incident Report Addendum (Form A–10B)	1,360	1	15	20,400
Significant Incident Report (Form A–10C)	80,340	1	20	1,606,800
Significant Incident Report Addendum (Form A–10D)	25,630	1	15	384,450
Sexual Abuse Significant Incident Report (Form A–10E)	5,980	1	20	119,600
Sexual Abuse Significant Incident Report Addendum (Form A–10F)	4,190	1	15	62,850
UAC Satisfaction Survey (Form A–11 & A–11s)	72,840	1	20	1,456,800
UAC Satisfaction Survey Aggregate Data	235	4	240	225,600
Hotline Alert (Form A–12)	80	1	15	1,200

Estimated Annual Burden Total: 3,982,800.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; *Flores* v. *Reno Settlement Agreement*, No. CV85–4544–RJK (C.D. Cal. 1996).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–07995 Filed 4–15–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3995]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Submission of Information on Pediatric Uses of Medical Devices

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 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 0910–0748. 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.

Submission of Information on Pediatric Uses of Medical Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure Under Section 515A of the Federal Food, Drug, and Cosmetic Act—21 CFR 814

OMB Control Number 0910–0748—Extension

Section 515A(a) of the Food, Drug, and Cosmetic Act (21 U.S.C. 360e-1) (FD&C Act) requires applicants who submit certain medical device applications to include readily available information providing a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. The information submitted will allow FDA to track the number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure and the review time for each such device application.

These requirements apply to applicants who submit humanitarian device exemption requests (HDEs), premarket approval applications (PMAs) or PMA amendments or supplements, or a product development protocol (PDP).

FDA expects to receive approximately 47 original PMA/PDP/HDE applications each year, 1 of which FDA expects to be HDEs. This estimate is based on the average of FDA's receipt of new PMA applications. The Agency estimates that 11 of the estimated 47 original PMA submissions will fail to provide the required pediatric use information and their sponsors will therefore be required to submit PMA amendments. The Agency also expects to receive approximately 928 supplements that will include the pediatric use information required by section 515A(a) of the FD&C Act and part 814 (21 CFR part 814).

All that is required is to gather, organize, and submit information that is readily available, using any approach that meets the requirements of section 515A(a) of the FD&C Act and part 814. We believe that because the applicant is required to organize and submit only readily available information, no more than 8 hours will be required to comply. Furthermore, because supplements may include readily available information on pediatric populations by referencing a previous submission, FDA estimates the average time to obtain and submit the required information is a supplement to be 2 hours. FDA estimates that the total estimated burden is 2,392 hours.

Additionally, the document entitled ''Providing Information About Pediatric Uses of Medical Devices—Guidance for Industry and Food and Drug Administration Staff'' describes how to

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]

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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,