Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: May 25, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–13084 Filed 6–2–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Migrant and Seasonal Head Start Study.

OMB No.: New Collection.

Description: The Office of Planning, Research and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is proposing an information collection activity for the Migrant and Seasonal Head Start (MSHS) Study.

The MSHS Study will describe the characteristics and experiences of the children and families who enroll in MSHS and the practices and services of the MSHS programs that serve them. The findings will provide up-to-date information to the Office of Head Start, other federal government agencies, local MSHS programs, and the public. The study will be the first national MSHS study to include direct child assessments, which will provide information about MSHS children that programs can use to inform program, center and classroom practices.

Data collection will involve mail surveys to selected MSHS center directors and all MSHS program directors nationwide about operational characteristics, program- and center-level policies and practices, and services and resources offered to MSHS families. The study will also conduct on-site data collection with children, parents, teachers, and classrooms in a nationally-representative sample of MSHS centers. The on-site data collection will include classroom observations, teacher surveys, child reports and child assessments.

Respondents: MSHS program directors, center directors, teachers, assistant teachers, parents, and children.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Estimated annual burden hours
Program Director survey	53	1	0.5	27
Center Director survey	253	1	0.5	127
Call script for Program Directors	24	1	1	24
Form for Program Directors to verify key information for selected centers	24	1	0.5	12
Call script for Center Directors	53	1	1	53
Call script for On Site Coordinators	53	1	1	53
Classroom sampling form	53	1	0.5	27
Child roster form	53	3	0.25	40
Teacher survey	159	1	0.5	80
Teacher child report	159	8	0.25	318
Assistant Teacher survey	159	1	0.25	40
Parent consent form	1,018	1	0.25	255
Child assessments (preschoolers and older toddlers only)	848	1	0.75	636
Parent interview (including Parent child report)	1,018	1	1	1,018

Estimated Total Annual Burden Hours: 2,710.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

ACF Certifying Officer.

[FR Doc. 2016–13104 Filed 6–2–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0628]

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

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 5, 2016.

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 *oira_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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Reporting Associated With New Animal Drug Applications (NADA)—21 CFR 514.1, 514.4, 514.5, 514.6, 514.8, 514.11, 558.5—OMB Control Number 0910–0032—Extension

Under Section 512(b)(1) of the Federal Food, Drug, and Cosmetic Act (the 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) 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 #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 pre-submission 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.

Finally, § 558.5(i) of our regulations (21 CFR 558.5(i)) describes the procedure for requesting a waiver of the labeling requirements of § 558.5(h) in the event that there is evidence to indicate that it is unlikely a new animal drug would be used in the manufacture of a liquid medicated feed.

The reporting associated with NADAs and related submissions is necessary to ensure that new animal drugs are in compliance with section 512(b)(1) of the FD&C Act. We use the information collected to review the data, labeling, and manufacturing controls and procedures to evaluate the safety and effectiveness of the proposed new animal drug.

In the *Federal Register* of March 2, 2016 (81 FR 10871), FDA 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 [1]

21 CFR Section; Activity	Number of respondents	Number of responses per respondent	Total annual responses	Avg. burden per response	Total hours
514.1 & 514.6; applications and amended applications	182	.05	9	212	1,908
514.1(b)(8) and 514.8(c)(1) [2]; evidence to establish safety and effectiveness	182	.10	19	90	1,710
514.5(b), (d), (f); requesting presubmission conferences	182	.49	89	50	4,450
514.8(b); manufacturing changes to an approved application	182	1.40	255	35	8,925
514.8(c)(1); labeling and other changes to an approved application	182	.05	10	71	710
514.8(c)(2) & (3); labeling and other changes to an approved application	182	.43	79	20	1,580
514.11; submission of data, studies and other information	182	.09	16	1	16
558.5(i); requirements for liquid medicated feed	182	.01	1	5	5
Form FDA 356V	182	2.92	531	5	2,655
TOTAL			1009		21,959

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

[2] NADAs and supplements regarding antimicrobial animal drugs that use a recommended approach to assessing antimicrobial concerns as part of the overall pre-approval safety evaluation.

Based on the number of sponsors subject to animal drug user fees, we estimate an average of 182 annual respondents during the 5 fiscal years, from October 1, 2010, through September 30, 2014, on which these estimates were made. We use this estimate consistently throughout the table and calculate the ''annual frequency per respondent'' by dividing the total annual responses by the total number of respondents. We base our

estimates of the average burden per response on our experience with NADAs and related submissions.

Dated: *May 27, 2016.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–13078 Filed 6–2–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0268]

Individual Patient Expanded Access Applications: Form FDA 3926; 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 guidance for industry entitled ''Individual Patient Expanded Access Applications: Form FDA 3926.'' The guidance describes Form FDA 3926 (Individual Patient Expanded Access—Investigational New Drug Application (IND)), which is available for licensed physicians to use for expanded access requests for individual patient INDs. Individual patient expanded access allows for the use of an investigational new drug outside of a clinical investigation, or the use of an approved drug where availability is limited by a risk evaluation and mitigation strategy (REMS), for an individual patient who has a serious or immediately life-threatening disease or condition when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition. Form FDA 3926 provides a streamlined alternative for submitting an IND for use in cases of individual patient expanded access, including for emergency use. This guidance finalizes the draft guidance issued in February 2015.

DATES: Submit either electronic or written comments on Agency guidances at any time.

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–2015–D–0268 for ''Individual Patient Expanded Access Applications: Form FDA 3926; Guidance for Industry; Availability.'' 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.

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; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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: Larry Lim, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., Rm. 4134, Silver Spring, MD 20993, 301–796–3146; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled