groups, online surveys, direct observation, and document review.

Respondents: Up to 18 early childhood centers will be invited to express interest in participating in the BSC. Up to 8 centers will be selected to participate in the BSC and feasibility study. Core BSC Teams consisting of up to 6 individuals (*e.g.,* directors, lead teachers, assistant teachers, teacher aides, parents, curriculum specialists, etc.) each from four Early Head Start or Head Start programs and four child care programs in a selected geographic location (for a total of 48 individuals); and up to 24 additional teachers or program staff at the same centers who are not part of the Core BSC Team.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
BSC Selection Questionnaire	18	9	1	1	9
Pre-Work Assignment: Team Building Activities	48	24	1	1	24
Pre-Work Assignment: Data Collection Planning Worksheet	16	8	1	2	16
Plan, Do, Study, Act Planning Form & Tracker	48	24	48	.25	288
Discussion Forum Prompts	48	24	48	.25	288
Learning Session Day 1 Evaluation	48	24	4	.17	16
Learning Session Overall Evaluation	48	24	4	.25	24
Action Planning Form	48	24	4	.25	24
Teaching Pyramid Observation Tool (TPOT)/Teaching Pyramid Infant-Toddler Observation Scale (TPITOS)	28	14	2	.33	9
Early Childhood Work Environment Survey (ECWES)	72	36	2	.25	18
Pre/Post Survey	72	36	2	.68	49
Self-report of BSC Activities	72	36	1	.17	6
Core BSC Team Focus Group Topic Guide	48	24	1	1.25	30

Estimated Total Annual Burden Hours: 801.

Additional Information: Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2017–23970 Filed 11–2–17; 8:45 am]

BILLING CODE 4184–23–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1147]

Controlled Correspondence Related to Generic Drug Development; Draft 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 draft guidance for industry entitled ''Controlled Correspondence Related to Generic Drug Development.'' This guidance provides information regarding the process by which generic drug manufacturers and related industry can submit controlled correspondence to FDA requesting information related to generic drug development and the Agency's process for providing communications related to such correspondence. This guidance also describes the process by which generic drug manufacturers and related industry can submit requests to clarify ambiguities in FDA' controlled correspondence response and the Agency's process for responding to those requests. This draft guidance revises the guidance for industry ''Controlled Correspondence Related to Generic Drug Development'' issued in September 2015.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 2, 2018.

ADDRESSES: You may submit comments as follows:

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–2014–D–1147 for ''Controlled Correspondence Related to Generic Drug Development; Draft Guidance for Industry; Availability.'' Received comments 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.

Submit written requests for single copies of the draft 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lisa Bercu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1611, Silver Spring, MD 20993–0002, 240–402–6902.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Controlled Correspondence Related to Generic Drug Development.'' This guidance provides information regarding the process by which generic drug manufacturers and related industry can submit to FDA controlled correspondence requesting information related to generic drug development and the Agency's process for providing communications related to such correspondence. This guidance also describes the process by which generic drug manufacturers and related industry can submit requests to clarify ambiguities in FDA's controlled correspondence response and the Agency's process for responding to those requests. In accordance with the Generic Drug User Fee Amendments (GDUFA) Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018–2022 (GDUFA II Goals Letter or GDUFA II Commitment Letter), FDA agreed to certain review goals and procedures for the review of controlled correspondence received both before, and on or after October 1, 2017.

The GDUFA II Commitment Letter defines standard controlled correspondence and complex controlled correspondence, and the draft guidance provides additional details and recommendations concerning what inquiries FDA considers controlled correspondence for the purposes of meeting the Agency's GDUFA II commitment. In addition, this guidance provides details and recommendations concerning what information requestors should include in a controlled correspondence to facilitate FDA's consideration of and response to a controlled correspondence and what information FDA will provide in its communications to requestors that have submitted controlled correspondence. The GDUFA II Commitment Letter also states that FDA will review and respond to requests to clarify ambiguities in the controlled correspondence response, and the guidance provides information on how requestors may submit these requests and the Agency's process for responding to them.

This guidance revises the guidance for industry ''Controlled Correspondence Related to Generic Drug Development'' issued in September 2015 available at: *https://www.fda.gov/downloads/drugs/guidances/ucm411478.pdf.* When finalized, this guidance will replace the September 2015 final guidance. Changes from the 2015 version include: Recommendations on requests concerning postapproval submission requirements and complex controlled correspondence, and information on how requestors can submit requests to clarify ambiguities in FDA's controlled correspondence response and the Agency's process for responding to those requests.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on controlled correspondence related to generic drug development. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title and description of the information collection are given under this section, with an estimate of the reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

We invite 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.

Title: Controlled Correspondence Related to Generic Drug Development—OMB Control Number 0910–0797—Revision.

Description: FDA has agreed to specific program enhancements and performance goals specified in the GDUFA II Commitment Letter. One of the performance goals applies to controlled correspondence related to generic drug development. The GDUFA II Commitment Letter includes details on FDA's commitment to respond to questions submitted as controlled correspondence within certain time frames. To facilitate FDA's prompt consideration of the controlled correspondence and to assist in meeting the prescribed time frames, FDA recommends including the following information in the inquiry: (1) Name, title, address, phone number, and entity of the person submitting the inquiry; (2) a letter of authorization, if applicable; (3) the FDA-assigned control number and submission date of any previous, related controlled correspondence that was accepted for substantial review and response, if any, as well as a copy of that previous controlled correspondence and FDA's response, if any; (4) the relevant reference listed drug(s), as applicable, including the application number, proprietary (brand) name, manufacturer, active ingredient, dosage form, and strength(s); (5) a statement that the controlled correspondence is related to a potential abbreviated new drug application (ANDA) submission to the Office of Generic Drugs, and the ANDA number, if applicable; (6) a concise statement of the inquiry; (7) a recommendation of the appropriate FDA review discipline; and (8) relevant prior research and supporting materials.

The GDUFA II Commitment Letter also includes details on FDA's commitment to respond to requests to clarify ambiguities in FDA's controlled correspondence response within certain time frames. To facilitate FDA's prompt consideration of the request, and to assist in meeting the prescribed time frames, FDA recommends including the following information in the inquiry: (1) Name, title, address, phone number, and entity of the person submitting the inquiry; (2) a letter of authorization, if applicable; (3) the FDA-assigned control number, submission date of the controlled correspondence on which the requestor is seeking clarification, a copy of that previous controlled correspondence, and FDA's response to the controlled correspondence; and (4) the clarifying questions and the corresponding section(s) of FDA's controlled correspondence response on which the requestor is seeking clarification.

The following information is based on inquiries considered controlled correspondence and submitted to FDA for fiscal years 2014, 2015, and 2016. FDA estimates approximately 390 generic drug manufacturers and related industry (*e.g.,* contract research organizations conducting bioanalytical or bioequivalence clinical trials) or their representatives would each submit an average of 3.8 inquiries annually for a total of 1,496 inquiries [1,496 ÷ 390 = 3.8]. Information submitted with each inquiry varies widely in content, depending on the complexity of the request. Inquiries that are defined as controlled correspondence may range from a simple inquiry on generic drug labeling to a more complex inquiry for a formulation assessment for a specific proposed generic drug product. As a result, these inquiries can vary between 1 to 10 burden hours, respectively.

Because the content of inquiries considered controlled correspondence is widely varied, we are providing an average burden hour for each inquiry. We estimate that it will take an average of 5 hours per inquiry for industry to gather necessary information, prepare the request, and submit the request to FDA. As a result, we estimate that it will take an average of 7,480 total hours annually for industry to prepare and submit inquiries considered controlled correspondence.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Submission of controlled correspondence	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Generic drug manufacturers, related industry, and representatives	390	3.8	1,496	5	7,480

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

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: October 30, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–23947 Filed 11–2–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0510]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Prohibited From Use in Animal Food or Feed

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