ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hour per response	Estimated annual burden hours
Classroom sampling form from Head Start staff	120	40	1	0.17	7
Child roster form from Head Start staff	120	40	1	0.33	13
Head Start core parent consent form	2,400	800	1	0.17	136
Head Start core child assessment	2,400	800	2	0.75	1,200
Head Start core parent survey	2,400	800	2	0.33	528
Head Start fall parent supplemental survey	2,400	800	1	0.08	64
Head Start core teacher child report	240	80	20	0.17	272
Total					2,220

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, 370 L'Enfant Promenade SW., Washington, DC 20447, 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, Fax: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Karl Koerper,

OPRE Reports Clearance, Officer.

[FR Doc. 2014–11054 Filed 5–13–14; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Head Start Impact Study Participants Beyond 8th Grade.

OMB No.: 0970–0229.

Description: The Administration for Children and Families (ACF) within the Department of Health and Human Services (HHS) will collect follow-up information from children and families in the Head Start Impact Study. In anticipation of conducting a future follow-up for the study, ACF will collect information necessary to identify respondent's current location and follow-up with respondents in the future.

The Head Start Impact Study is a longitudinal study involving 4,667 first-time enrolled three- and four-year-old preschool children across 84 nationally representative grantee/delegate agencies (in communities where there were more eligible children and families than can be served by the program). Participants were randomly assigned to either a Head Start group (that could enroll in Head Start services) or a control group (that could not enroll in Head Start services but could enroll in other available services selected by their parents). Data collection for the study began in fall of 2002 and continued through late spring 2008 to include the participants' 3rd grade year. Location and contact information for participants has been collected every spring beginning in 2009 and continued through spring 2014.

ACF will continue to collect a small amount of information for the sample through the spring of the participant's 12th grade year. To maintain adequate sample size, telephone interviews (with in-person follow-up as necessary) will be conducted in order to update the children's status and their location and contact information. This information will be collected from parents or guardians in the spring of 2015 and 2016. Updates will take about 20 minutes to complete.

Respondents: The original sample of 4,667 treatment and control group members in the Head Start Impact Study, less 432 families that have given a ''hard'' refusal to participate in the study (e.g., adamantly refused to participate or threatened interviewers if they were contacted again). The number of respondents for this requested data collection is 4,235.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Parent Tracking Interview	4235	1	1/3	1412

Estimated Total Annual Burden Hours: 1412.

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, 370 L'Enfant Promenade SW., Washington, DC 20447, 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.

Karl Koerper,

Reports Clearance, Officer.

[FR Doc. 2014–11055 Filed 5–13–14; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0234]

Draft Guidance for Industry on Clinical Pharmacology Data To Support a Demonstration of Biosimilarity to a Reference Product; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product.'' This guidance is intended to assist sponsors in developing a clinical pharmacology program to support a decision that a proposed therapeutic biological product is *biosimilar* to, that is not clinically meaningfully different from, its reference product. Specifically, the guidance discusses some of the overarching concepts related to clinical pharmacology studies for biosimilar products, approaches for developing the appropriate clinical pharmacology database, and the utility of modeling and simulation for designing clinical trials. This draft guidance is one in a series of guidances that FDA is developing to implement the Biologics Price Competition and Innovation Act of 2009 (BPCI Act).

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 August 12, 2014.

ADDRESSES: 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, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002, or Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. 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.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6340, Silver Spring, MD 20993–0002, 301–796–2500, email: *sandra.benton@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product.'' Clinical pharmacology studies are part of a stepwise approach to develop the data and information needed to support a demonstration of biosimilarity. Adequate and well-conducted clinical pharmacology studies can address the residual uncertainty in biosimilarity assessment from clinical perspectives and inform the design of subsequent studies to assess clinically meaningful differences between the biosimilar and the reference products. The draft guidance discusses some critical considerations related to clinical pharmacology testing for biosimilar products, approaches for developing the appropriate clinical pharmacology database, and the utility of modeling and simulation for designing clinical trials. In its description of how to design and use clinical pharmacology studies to add to the totality of evidence that a proposed biological product is biosimilar to its reference product, the draft guidance is meant to assist sponsors in designing such studies in support of applications submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)). Scientific principles described in the draft guidance may also be informative for the development of certain biological products under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

This draft guidance is one in a series that FDA is developing to implement the BPCI Act and is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information submitted under section 351(k) applications for biosimilars is approved under OMB control number 0910–0719. The collection of information submitted under 21 CFR part 312 is approved under OMB control number 0910–0014.

III. Comments

Interested persons may submit either electronic comments regarding the draft guidance to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

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