ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN—Continued

Section and activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
121.9(b) Designated Transplant Program Requirements	10	1	10	5.0	50
121.9(d) Appeal for designation	2	1	2	6	12
Total	3,014		36,524		20,063

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: October 7, 2010.

Wendy Ponton,

Director, Office of Management.

[FR Doc. 2010–25843 Filed 10–13–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office at (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project Title: Evaluation of the National Healthy Start Program—[NEW]

Background: The National Healthy Start Program, funded through the Health Resources and Services Administration's (HRSA) Maternal and Child Health Bureau (MCHB), was developed in 1991 with the goal of reducing infant mortality disparities in high-risk populations through community-based interventions. The program originally began as a five-year demonstration project within 15 communities that had infant mortality rates 1.5 to 2.5 times above the national average.

The National Healthy Start Program has since expanded in size and mission to include 102 grantees across the nation, emphasizing a community-based, culturally competent approach to the delivery of care for women and their babies. MCHB seeks to conduct a cross-site evaluation of all Healthy Start grantees to document the accomplishments made by the National Healthy Start Program.

Purpose: The purpose of the survey is to collect consistent data on the services and activities of all 102 Healthy Start grantees. The data collected though this survey will be used to:

- Evaluate the grantees' performance and progress toward achieving short-term and long-term goals;
- Evaluate the relationship of performance and progress to implementation features of Healthy Start Program components;
- Assist MCHB in determining on a national level where technical assistance may be needed to improve program performance, set future priorities for program activities, and contribute to the overall strategic planning activities of MCHB; and
- Provide foundation data for future measurement of the initiative's long-term impact.

Respondents: The project directors of Healthy Start grants funded by HRSA will be the respondents for this data collection activity. The estimated response burden is as follows:

	No. of respondents	Responses per respondent	Total responses	Average hours per respondent	Total burden hours
Healthy Start Grantee Web Survey	102	1	102	4.0	408
Total	102	1	102	4.0	408

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: October 7, 2010.

Wendy Ponton,

Director, Office of Management.

[FR Doc. 2010–25841 Filed 10–13–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0500]

Draft Guidance for Industry: Early Clinical Trials With Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Early Clinical Trials with Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information" dated September 2010. The draft guidance provides investigational new drug application (IND) sponsors with recommendations on the submission of INDs for early clinical trials with live biotherapeutic products (LBPs).

DATES: Although you can comment on any guidance at any time (21 CFR 10.115(g)(5)), to ensure that the agency considers your comments 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 December 13, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. *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: Benjamin A. Chacko, 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 document entitled "Guidance for Industry: Early Clinical Trials with Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information" dated September 2010. The draft guidance provides IND sponsors with recommendations on the submission of INDs for early clinical trials with LBPs.

Regulations in part 312 (21 CFR part 312) require sponsors who wish to study LBPs in humans to submit an IND to FDA, unless the sponsor falls into one of the exemptions for clinical investigations found under § 312.2(b). The general principles underlying the IND submission and the general requirements for an IND's content and format are contained in §§ 312.22 and 312.23, respectively. This draft guidance focuses on the chemistry, manufacturing, and control information that should be provided in an IND in order to meet the requirements under § 312.23 for early clinical trials evaluating LBPs. This draft guidance is applicable to all INDs of LBPs, whether clinical trials are conducted commercially, in an academic setting, or otherwise (§ 312.2).

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA'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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 312 have been approved under the Office of Management and Budget (OMB) control number 0910–0014.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

IV. Electronic Access

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

Dated: October 7, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–25850 Filed 10–13–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0503]

Draft Guidance for Industry on Investigational New Drug Applications—Determining Whether Human Research Studies Can Be Conducted Without an Investigational New Drug Application; 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 "Investigational New Drug Applications (INDs)—Determining Whether Human Research Studies Can Be Conducted Without an IND." This draft guidance is intended to assist clinical investigators, sponsors, and sponsor-investigators in determining whether planned human research studies must be conducted under an investigational new drug application (IND). The guidance describes the basic criteria for when an IND is required, describes specific situations in which an IND is not required, and discusses a range of issues that, in FDA's experience, have been the source of confusion or misperceptions about the application of the IND requirements.

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 comments 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 12, 2011. Submit either electronic or written comments concerning proposed collection of information by December 13, 2010.

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 the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation Research (CBER), Food and Drug Administration, 1401