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.