FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Submission of information for de novo petition program	Number of respondents	Number of responses per respondent per year	Total annual responses	Average burden per respondent (in hours)	Total hours
CDRH	25	1	25	100	2,500
CBER	1	1	1	100	100
Total					2,600

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

Respondents are medical device manufacturers seeking to market medical device products that have been classified into class III under section 513(f)(2) of the FD&C Act. Based on FDA's experience with the de novo petition program, FDA expects the program to continue to be utilized as a viable program in the future. It is expected that the number of petitions will increase over its current rate and reach a steady rate of approximately 26 submissions per year

FDA estimates from past experience with the de novo petition program that the complete process involved with the program takes approximately 100 hours. This average is based upon estimates by FDA administrative and technical staff who are familiar with the requirements for submission of a de novo petition (and related materials), have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted.

Therefore, the total reporting burden hours is estimated to be 2,600 hours.

TABLE 2

Number of respondents	Total burden hours annualized	Hourly wage rate	Total cost annualized
26	100	$150	$390,000

The average to industry per hour for this type of work is $150, resulting in a cost of $15,000 per respondent. The estimated submission cost of $15,000 multiplied by 26 submissions per year equals $390,000, which is the aggregated industry reporting cost annualized.

This draft guidance also refers to currently approved information collections found in FDA regulations. The collections of information in 21 CFR part 807, subpart E, are approved under OMB control number 0910–0120.

V. Comments

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.

Dated: September 27, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–25367 Filed 9–30–11; 8:45 am]

BILLING CODE 4160–01–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, 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, call the HRSA Reports Clearance Office at (301) 443–1129. The following request has been submitted to OMB for review under the Paperwork Reduction Act of 1995:

Proposed Project: ADAP Data Report—[New]

HRSA's AIDS Drug Assistance Program (ADAP) is funded through the Ryan White HIV/AIDS Program, Part B, of Title XXVI of the Public Health Service Act, which provides grants to states and territories. Each of the 50 states, the District of Columbia, Puerto Rico, and several territories receive ADAP grants. The ADAP provides medications for the treatment of HIV/AIDS. Program funds may also be used to purchase health insurance for eligible clients or for services that enhance access, adherence, and monitoring of drug treatments.

The Ryan White HIV/AIDS Program specifies HRSA's responsibilities in the administration of grant funds, the allocation of funds, the evaluation of programs for the population served, and the improvement of quality of care. Accurate records of the grantees receiving Ryan White HIV/AIDS Program funding, the services provided, and the clients served, continue to be critical issues for the implementation of the legislation and are necessary for HRSA to fulfill its responsibilities.

The ADAP Data Report (ADR) provides data on the characteristics of ADAP grantees and the clients being served with program funds. The ADR is

intended to support clinical quality management, performance measurement, service delivery, and client monitoring at the system and client levels. The reporting system consists of an online data form—the Grantee Report—and a data file containing the client-level data elements. Data will be submitted every six months. The Grantee Report includes information about program administration, funding, and expenditures, in addition to the medication formulary. The client-level data include demographic, clinical, enrollment, and service data for each patient who is determined eligible and enrolled in the ADAP.

The legislation specifies grantee accountability and links budget to performance. The ADR will be used to ensure compliance with the requirements of the legislation, to evaluate the progress of programs, to monitor grantee performance, to measure the Government Performance and Results Act (GPRA) and the Performance Assessment Rating Tool (PART) goals, and to meet reporting responsibilities to the Department, Congress, and OMB.

In addition to meeting the goal of accountability to Congress, clients, advocacy groups, and the general public, information collected through the ADR is critical to HRSA and grantees for assessing the status of existing HIV-related service delivery systems, investigating trends in service utilization, and identifying the areas of greatest need.

Discussions were held with nine volunteer grantee agencies representing a variety of ADAP models, as a basis for the burden estimates for the ADR that follows. These burden estimates are presented in two tables. The first table represents the estimated burden for the first year, including the estimated time to adjust existing or develop new data collection systems to collect the elements that HRSA is requesting. This is a one-time burden for grantees and will not be a factor after the first year. The second table represents the estimated burden for subsequent years. The Grantee Report burden remains unchanged across the three years of the information collection, as the submission is consistent with current reporting requirements. The Client Report burden is expected to decrease slightly in subsequent years as grantees become more proficient with reporting client-level data, based on feedback and technical assistance resources that HRSA will provide.

The annual estimate of burden for the first year of the information collection is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Grantee Report	57	2	114	12.50	1,425.00
Client Report	57	2	114	34.19	3,897.66
Data Collection System	57	1	57	826.00	47,082.00
Total:					52,404.66

The annual estimate of burden for subsequent years is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Grantee Report	57	2	114	12.50	1,425.00
Client Report	57	2	114	24.00	2,736.00
Total:					4,161.00

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 e-mail 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: September 26, 2011.

Wendy Ponton,

Director, Office of Management.

[FR Doc. 2011–25339 Filed 9–30–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Intent To Prepare an Environmental Impact Statement

Summary: In accordance with the National Environmental Policy Act, the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS), is issuing this notice to advise the public that an environmental impact statement will be prepared for the NIH Animal Center at Poolesville Master Plan, Poolesville, Montgomery County, Maryland.

For Further Information Contact: Valerie Nottingham, Chief, Environmental Quality Branch, Division of Environmental Protection, Office of Research Facilities, NIH, B13/2S11, 9000 Rockville Pike, Bethesda, Maryland 20892, telephone 301–496–7775; fax 301–480–8056; or e-mail *nihnepa@mail.nih.gov*.

Supplementary Information: The NIH Animal Center is located on 513 acres 4 miles southwest of the City of Poolesville, a small agricultural community located in western Maryland. The campus is a component of the National Institutes of Health (NIH), one of the world's largest biomedical research facilities and the Federal government's focal point for medical and behavioral research. The NIH Animal Center at Poolesville is a major extension of animal holding and production facilities at Bethesda and consists of a number of buildings used to house, quarantine, and study the