the practical utility of the information to be collected.

FDA acknowledges one request for additional details on the information to be collected and the planned research methodology, but notes that its notice asked for comment on FDA's request for a generic clearance to collect information related to the formative pretesting of tobacco communication messages. Under this generic clearance, details of individual studies will be tailored to specific communications-related questions. For each study FDA would request under this clearance, FDA will provide OMB with details on the information collection (e.g., research question(s), methodology). The communication development process will inform the purpose of the data collection and hence its methodology. For very early message development, qualitative research such as focus groups or in-depth interviews will be appropriate. At later communications development stages, qualitative as well as more quantitative data collection may be needed.

One comment noted that FDA separately requested comment on a specific study of the efficacy of graphic cigarette warning labels (Docket No. FDA–2010–N–0079). In response to this comment, and to avoid apparent duplication of effort, FDA agrees that it will not conduct any pretesting of tobacco warning labels under this proposed generic clearance. Further, FDA will not use studies conducted under this generic clearance to make regulatory policy or enforcement decisions. However, FDA may conduct research under this generic clearance concerning the development of informational campaigns that FDA may undertake to explain changes to, and the implications of, tobacco product warning label regulations.

After careful consideration, FDA determined that a comment suggesting limiting pretesting to adults to minimize the burden of information collections on the public would reduce the utility of study results. This suggestion goes against commonly accepted communication practice, and the advice of FDA's Risk Communication Advisory Committee, to target intended audiences with messages tailored to their specific needs. Segmenting pretesting by audience will produce results that will better inform FDA's development of messages relevant to intended audiences' specific needs, beliefs, and attitudes. A major objective of FDA tobacco communications will be to discourage tobacco use by adolescents before they start. Therefore, it is critical that FDA understand the decisionmaking processes among 13 to 17 year olds. Also, the suggestion to eliminate the pretesting of messages delivered across multiple platforms (e.g., television, print, radio) ignores a fundamental research goal of matching appropriate messages with effective distribution channels. Limiting pretesting in this way would leave FDA basing its communication activities on assumptions rather than science-based research.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Type of Respondents	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Adolescents 13 to 17, adults 18+, health care professionals, tobacco retailers	16,448	1	16,448	0.1739	2,860
Total	16,448				2,860

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

Dated: August 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19356 Filed 8–5–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0199]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Procedures for the Clinical Laboratory Improvement Amendments of 1988 Categorization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 7, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0607. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Administrative Procedures for the Clinical Laboratory Improvement Amendments of 1988 Categorization—(OMB Control Number 0910–0607; Extension)

A guidance document entitled "Guidance for Administrative Procedures for CLIA Categorization" was released on May 7, 2008. The document describes procedures FDA will use to assign the complexity category to a device. Typically, FDA assigns complexity categorizations to devices at the time of clearance or approval of the device. In this way, no additional burden is incurred by the manufacturer since the labeling (including operating instructions) is included in the 510(k) or Premarket Application. In some cases, however, a manufacturer may request CLIA categorization even if FDA is not

simultaneously reviewing a 510(k) or PMA. One example is when a manufacturer requests that FDA assign CLIA categorization to a previously cleared device that has changed names since the original CLIA categorization. Another example is when a device is exempt from premarket review. In such cases, the guidance recommends that manufacturers provide FDA with a copy of the package insert for the device and a cover letter indicating why the manufacturer is requesting a categorization (e.g. name change, exempt from 510(k) review). The guidance recommends that in the correspondence to FDA the manufacturer should identify the product code and classification as well as reference to the original 510(k) when this is available. The number of respondents is approximately 60. On average, each respondent will request categorizations (independent of a 510(k) or PMA) 15 times per year. The cost, not including personnel, is estimated at $52 per hour (52 x 900) totaling $46,800. This includes the cost of copying and mailing copies of package inserts and a cover letter, which includes a statement of the reason for the request and reference to the original 510(k) numbers, including regulation numbers and product codes. The burden hours are based on FDA familiarity with the types of documentation typically included in a sponsor's categorization requests, and costs for basic office supplies (e.g. paper). The costs have been updated based on the Bureau of Labor Statistics estimates of inflation.

In the **Federal Register** of May 4, 2010 (75 FR 23781), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

42 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Responses	Total Hours	Total Operating & Maintenance Costs
42 CFR 493.17	60	15	900	1	900	$46,800

[1] There are no capital costs associated with this collection of information.

Dated: August 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19358 Filed 8–5–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0394]

Clinical Studies of Safety and Effectiveness of Orphan Products Research Project Grant (R01)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of FDA's Office of Orphan Products Development (OPD) grant program. The goal of FDA's OPD grant program is to support the clinical development of products for use in rare diseases or conditions where no current therapy exists or where the proposed product will be superior to the existing therapy. FDA provides grants for clinical studies on safety and/or effectiveness that will either result in, or substantially contribute to, market approval of these products. Applicants must include in the application's Background and Significance section documentation to support the estimated prevalence of the orphan disease or condition (or in the case of a vaccine or diagnostic, information to support the estimates of how many people will be administered the diagnostic or vaccine annually) and an explanation of how the proposed study will either help support product approval or provide essential data needed for product development.

DATES: Important dates are as follows:

1. The application due dates are February 2, 2011; February 1, 2012. The resubmission due dates are October 14, 2011; October 15, 2012.
2. The anticipated start dates are November 2010; November 2012.
3. The opening date is December 2, 2010.
4. The expiration date is February 2, 2012; October 16, 2012 (resubmission).

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:

Katherine Needleman, Orphan Products Grants Program, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5271, Silver Spring, MD 20993–0002, 301–796–8660, e-mail: *katherine.needleman@fda.hhs.gov.*

Vieda Hubbard, Division of Acquisition Support and Grants, Office of Acquisitions & Grant Services, 5630 Fishers Lane, Rockville, MD 20857, 301–827–7177, e-mail: *vieda.hubbard@fda.hhs.gov.*

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *http://grants.nih.gov/grants/guide* (select the "Request for Applications" link), *http://www.grants.gov* (see "For Applicants" section), and *http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/WhomtoContactaboutOrphanProductDevelopment/ucm134580.htm.*[1]

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–11–001
93.103

A. Background

The OPD was created to identify and promote the development of orphan products. Orphan products are drugs, biologics, medical devices, and medical foods that are indicated for a rare disease or condition (that is, one with prevalence, not incidence, of fewer than 200,000 people in the United States). Diagnostics and vaccines will qualify for orphan status only if the U.S. population to whom they will be administered is fewer than 200,000 people per year.

B. Research Objectives

The goal of FDA's OPD grant program is to support the clinical development of products for use in rare diseases or conditions where no current therapy exists or where the proposed product will be superior to the existing therapy. FDA provides grants for clinical studies on safety and/or effectiveness that will either result in, or substantially contribute to, market approval of these

[1] FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)