TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
200	30	6,000	.5	3,000

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

FDA projects 30 emergency risk related surveys per year with a sample of between 50 and 200 respondents per survey. FDA also projects a response time of 0.5 hours per response. These estimates are based on the maximum sample size per questionnaire that FDA can analyze in a timely manner. The annual frequency of response was determined by the maximum number of questionnaires that will be sent to any individual respondent. Some respondents may be contacted only one time per year, while other respondents may be contacted several times annually, depending on the human drug, biologic, or medical device under evaluation. It is estimated that, given the expected type of issues that will be addressed by the surveys, it will take 0.5 hours for a respondent to gather the requested information and fill in the answers.

Dated: August 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19357 Filed 8–5–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0084]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Pretesting of Tobacco Communications

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–NEW and the title "Pretesting of Tobacco Communications." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *JonnaLynn.Capezzuto@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.

Pretesting of Tobacco Communications—0910–NEW

In order to conduct educational and public information programs relating to tobacco use, as authorized by section 1003(d)(2)(D) of the Federal Food Drug and Cosmetic Act (21 U.S.C. section 393) and to develop effective tobacco-related communications as authorized by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), FDA must conduct research and studies relating to the control and prevention of disease (also authorized by section 301 of the Public Health Service Act (42 U.S.C 241(a)). In conducting such research, FDA will employ formative pretests to assess the likely effectiveness of tobacco communications with specific target audiences. The information collected will serve two major purposes. First, formative research will provide critical knowledge about target audiences such as adolescents, adults, health care professionals, and tobacco retailers. FDA must first understand critical influences on people's decisionmaking process when choosing to use, not use, or quit using tobacco products. In addition to understanding the decisionmaking processes of adults, it is also critical to understand the decisionmaking processes among adolescents (ages 13 to 17), where communications will aim to discourage tobacco use before it starts. FDA must also understand the general beliefs of retailers in the tobacco product supply chain. Retailers play a key role in the success of tobacco control as they are directly impacted by many of the regulations FDA will issue under the Tobacco Control Act. FDA must determine retailers' informational needs and the most effective communication channels and formats for reaching and educating them about new regulations. This knowledge will allow FDA to engage retailers as partners in tobacco control by better equipping them with the tools needed to comply with these regulations. FDA will apply knowledge of these decisionmaking processes to design effective communication strategies and messages. Second, initial testing will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Pretesting messages with a sample of the target audience will allow FDA to refine messages while they are still in the developmental stage. By utilizing appropriate qualitative and quantitative methodologies, FDA will be able to: (1) Better understand characteristics of the target audience—its attitudes, beliefs, and behaviors—and use these in the development of effective risk communications; (2) more efficiently and effectively design messages and select formats that have the greatest potential to influence the target audience's attitudes and behavior in a favorable way; (3) determine the best promotion and distribution channels to reach the target audience with appropriate messages; and (4) expend limited program resource dollars wisely and effectively.

In the **Federal Register** of March 1, 2010 (75 FR 9225), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received comments from four public entities, including two corporations, one nonprofit organization, and one city health department. Comments supported FDA taking a science-based approach to its communication activities. None of the comments objected to the estimated annual reporting burden or questioned

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]

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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