

Elaine L. Baker, MPH, DLP,
 Director, Management Analysis and Services
 Office, Centers for Disease Control and
 Prevention (CDC).

[FR Doc. 2016-21400 Filed 9-6-16; 8:45 am]

BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND
 HUMAN SERVICES**

Food and Drug Administration

[Docket No. FDA-2013-N-0514]

**Agency Information Collection
 Activities; Submission for Office of
 Management and Budget Review;
 Comment Request; Requests for
 Clinical Laboratory Improvement
 Amendments 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 October 7,
 2016.

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 emailed 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: FDA
 PRA Staff, Office of Operations, Food
 and Drug Administration, Three White
 Flint North 10A-12M, 11601
 Landsdown St., North Bethesda, MD
 20852, *PRAStaff@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.

**Requests for Clinical Laboratory
 Improvement Amendments of 1988
 Categorization—42 CFR 493.17—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
 uses 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

because the labeling (including
 operating instructions) is included in
 the premarket notification (510(k)) or
 premarket approval application (PMA).
 In some cases, however, a manufacturer
 may request Clinical Laboratory
 Improvement Amendments of 1998
 (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.

In the **Federal Register** of April 27,
 2016 (81 FR 24820), FDA published a
 60-day notice requesting public
 comment on the proposed collection of
 information. No comments were
 received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Request for CLIA Categorization	60	15	900	1	900	\$46,800

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

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 × 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).

Dated: August 31, 2016.
Leslie Kux,
 Associate Commissioner for Policy.
 [FR Doc. 2016-21352 Filed 9-6-16; 8:45 am]
BILLING CODE 4164-01-P

**DEPARTMENT OF HEALTH AND
 HUMAN SERVICES**

Food and Drug Administration

[Docket No. FDA-2013-N-0731]

**Agency Information Collection
 Activities; Proposed Collection;
 Comment Request; Human Cells,
 Tissues, and Cellular and Tissue-
 Based Products: Establishment
 Registration and Listing; Eligibility
 Determination for Donors; and Current
 Good Tissue Practice**

AGENCY: Food and Drug Administration,
 HHS.

ACTION: Notice.