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Dated: September 12, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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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 16, 2013.

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, 1350 Piccard Dr., P150-400B, Rockville, MD 20850, *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 (CLIA) 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 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 May 22, 2013 (78 FR 30312), 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 ACTIVITY ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	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: September 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA’s regulatory issues.

Date and Time: The meeting will be held on November 1, 2013, from 8 a.m. to 4:30 p.m.

Location: FDA Fishers Lane Building, 5630 Fishers Lane, rm. 1066, Rockville, MD 20857. For those unable to attend in person, the meeting will also be Web cast. The Web cast will be available at the following link: <http://fda.yorkcast.com/webcast/Viewer/?peid=18390c01dff405681afa644b1837e5a1d>.

Contact Person: Bryan Emery or Pearlina Muckelvene, Center for Biologics Evaluation