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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.
[FR Doc. 2013-22443 Filed 9-13-13; 8:45 am]
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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

and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-1277 or 301-827-1281, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On the morning of November 1, 2013, the committee will meet in open session to discuss MP Biomedicals' biologic license application for the MP Diagnostics HTLV Blot 2.4, a Western Blot intended for use as a confirmatory test for blood donors. In the afternoon, the committee will hear update presentations on the following topics: (1) The April 2013 FDA public workshop on multiplex detection of transfusion transmissible agents and blood cell antigens in blood donations and (2) FDA safety communications on new boxed warnings for immune globulin products and hydroxyethyl starch solutions. Following the update presentations, the committee will meet in open session to hear presentations on the research programs of the Laboratory of Biochemistry and Vascular Biology, Division of Hematology, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: On November 1, 2013, from 8 a.m. to approximately 4 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 24, 2013. Oral presentations from the public will be scheduled between approximately 11 a.m. and 11:30 a.m. Afternoon presentations will be scheduled between approximately 3:30 p.m. and 4 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 16, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is

greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 17, 2013.

Closed Committee Deliberations: On November 1, 2013, from approximately 4 p.m. to 4:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss the site visit report of the intramural research programs and make recommendations regarding personnel staffing decisions.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets. Seating for this meeting may be limited, so the public is encouraged to watch the free Web cast if you are unable to attend. The Web cast will be available at 8 a.m. on November 1, 2013, at the link provided.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Bryan Emery at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 9, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Antiviral Drugs 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). The meeting will be open to the public.

Name of Committee: Antiviral Drugs 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 October 25, 2013, from 8 a.m. to 5 p.m.

Location: Sheraton Silver Spring Hotel, Cypress Ballroom, 8777 Georgia Ave., Silver Spring, MD. The hotel phone number is 301-589-0800.

Contact Person: Karen Abraham-Burrell, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: AVAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 204671, sofosbuvir (an NS5B polymerase inhibitor), manufactured by Gilead Sciences, Inc., with a proposed indication for the treatment of chronic hepatitis C infection, in combination with other agents in adult patients with genotypes 1 to 6 and/or adult patients awaiting liver transplantation.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 9, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 1, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public