

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <http://www.regulations.gov>.

Dated: November 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-27770 Filed 11-19-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1358]

Draft Guidance for Industry: Recommendations for Premarket Notification (510(k)) Submissions for Nucleic Acid-Based Human Leukocyte Antigen Test Kits Used for Matching of Donors and Recipients in Transfusion and Transplantation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Recommendations for Premarket Notification (510(k)) Submissions for Nucleic Acid-Based Human Leukocyte Antigen (HLA) Test Kits Used for Matching of Donors and Recipients in Transfusion and Transplantation" dated November 2013. The draft guidance document provides recommendations to submitters and FDA reviewers in preparing and reviewing 510(k) submissions for nucleic acid-based HLA

test kits used for matching of donors and recipients in transfusion and transplantation. The guidance provides detailed information on the types of studies FDA recommends for validation of HLA test kits submitted as 510(k)s.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 18, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John Reilly, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Recommendations for Premarket Notification (510(k)) Submissions for Nucleic Acid-Based Human Leukocyte Antigen (HLA) Test Kits Used for Matching of Donors and Recipients in Transfusion and Transplantation" dated November 2013.

The draft guidance provides recommendations to submitters and FDA reviewers in preparing and reviewing 510(k) submissions for nucleic acid-based HLA test kits used for the matching of donors and recipients in transfusion and transplantation, whether testing is for a single locus or for multiple loci simultaneously. This includes detailed information on the types of studies FDA recommends for validation of HLA test

kits submitted as 510(k)s. The guidance document addresses the types of studies and other information that FDA recommends be used in designing and conducting studies for validation of nucleic acid-based HLA test kits and preparing a 510(k) submission.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 809 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 812 have been approved under OMB control numbers 0910-0078 and 0910-0582; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; the collections of information in 21 CFR part 56 have been approved under OMB control number 0910-0130; and the collections of information in 21 CFR part 50 have been approved under OMB control number 0910-0586.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: November 14, 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]

Changing Regulatory and Reimbursement Paradigms for Medical Devices in the Treatment of Obesity and Metabolic Diseases: How To Estimate and Reward True Patient-Centric Value in Innovation; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled “Changing Regulatory and Reimbursement Paradigms for Medical Devices in the Treatment of Obesity and Metabolic Diseases: How to Estimate and Reward True Patient-Centric Value in Innovation.” FDA is cosponsoring the workshop with the American Gastroenterological Association (AGA). The purpose of the workshop is to facilitate discussion between FDA, AGA, and other interested parties of the development of medical devices for the treatment of morbid obesity and other metabolic diseases and evolving approaches for the regulation and reimbursement of minimally invasive procedures. The public workshop is being rescheduled due to the government shutdown. The title of the workshop has also been changed.

DATES AND TIMES: The public workshop will be held on December 19, 2013, from 8:30 a.m. to 5 p.m. and on December 20, 2013, from 8:30 a.m. to 12:15 p.m.

Location: The public workshop will be held at the Grand Hyatt Washington, DC, 1000 H St. NW., Washington, DC 20001, 202-582-1234.

Contact Person: Herbert Lerner, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66,

Rm. G114, Silver Spring, MD 20993-0002, 301-796-6511, email: herbert.lerner@fda.hhs.gov.

Registration: Registration is limited and is available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. (EDT), December 10, 2013. Onsite registration will be available after this date. To register for the public workshop, please visit the American Gastroenterological Association (AGA) Web site: <http://www.gastro.org/education-meetings/live-meetings/aga-fda-regulation-and-reimbursement-workshop>. For more information on the workshop, please see the FDA’s Medical Devices News & Events—Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.)

The AGA will collect a registration fee to cover its share of the expenses associated with the public workshop, which is included in the registration information on the AGA Web site.

If you need special accommodations due to a disability, please contact Herbert Lerner (see *Contact Person*) at least 7 days before the public workshop.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of the public workshop is to facilitate discussion between FDA, the AGA and other interested parties on the issues of device development, public and private payer reimbursement, venture capital, and regulatory pathways for device innovation and marketing. The workshop will provide a forum for discussing new approaches for the treatment of morbid obesity and other metabolic diseases as well as evolving approaches for the regulation and reimbursement of minimally invasive procedures.

II. Topics for Discussion at the Public Workshop

Topics to be discussed at the public workshop include, but are not limited to:

- Challenges to MedTech Innovation in the United States;
- Evolving Approaches for the Regulation of Minimally Invasive Procedures: The FDA Benefit/Risk Paradigm;
- Evolving Approaches for the Reimbursement of Minimally Invasive Procedures: How to Put a Price on Value;

- Obesity as a Disease: Redefining the Regulatory and Reimbursement Context; and

- The “Process”—Investigational Device Exemption Review.

Dated: November 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 10-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: The National Health Service Corps and NURSE Corps Interest Capture Form.

OMB No.: 0915-0337—Revision.

Abstract: The National Health Service Corps (NHSC) and the NURSE Corps of