

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: May 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-11685 Filed 5-14-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Food and Drug Administration-American Urological Association-Society of Urologic Oncology Workshop on Partial Gland Ablation for Prostate Cancer; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled “AUA-FDA-SUO Workshop on Partial Gland Ablation for Prostate Cancer.” The topics to be discussed are the technologies and imaging used in partial gland ablation, and the design of clinical trials to measure the most appropriate endpoints for partial gland ablation for prostate cancer. The workshop will be part of the American Urological Association (AUA) annual meeting in New Orleans, LA.

DATES: The public workshop will be held on Sunday, May 17, 2015, from 1 p.m. to 6 p.m.

ADDRESSES: The workshop will be held at the New Orleans Ernest N. Morial Convention Center, 900 Convention Center Blvd., New Orleans, LA 70130.

Registration: Persons interested in attending this workshop must register online for the AUA annual meeting. The facilities are limited and, therefore, attendance may be limited. To register for the workshop, please visit the AUA Web site, <http://www.aua2015.org/register/>.

If you need special accommodations due to a disability, please contact Ms. Susan Monahan, 301-796-5661, email: susan.monahan@fda.hhs.gov.

For more information on the workshop, please visit FDA’s Medical Devices News & Events—Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this workshop from the posted events list.) No commercial or promotional material will be permitted to be presented or distributed at the workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management between 9 a.m. and 4 p.m. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> (select this workshop from the posted events list), approximately 45 days after the workshop.

FOR FURTHER INFORMATION CONTACT: John Baxley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G210, Silver Spring, MD 20993, 301-796-6549, email: john.baxley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA’s Center for Devices and Radiological Health, the AUA, and the Society of Urologic Oncology (SUO) are cosponsoring this workshop. The purpose is to provide a forum to discuss the development of products that ablate prostatic tissue, particularly products that target ablation to regions of known cancer while intentionally sparing the remainder of the prostate from treatment.

The majority of cases of prostate cancer diagnosed in the United States represent low risk, organ-confined disease, which may be overtreated if conventional treatment methods (*i.e.*, radical prostatectomy and whole gland radiation therapy) are employed. Over the past decade, partial gland ablation therapies have emerged as treatment alternatives that can spare patients from many of the undesired side effects associated with standard, radical treatment. However, multiple challenges currently impede the adoption of partial gland ablation technologies, including

the long natural history associated with this disease, imprecision in accurately diagnosing and targeting the tumor regions, and the lack of validated biomarkers or surrogate endpoints to establish clinical benefit in a reasonable period of time.

The purposes of this public workshop are to: (1) Foster collaboration and receive input from experts within the scientific community; (2) obtain input from various stakeholders including patients, investigators and industry regarding the development of minimally invasive devices to ablate prostatic tissue; (3) foster clinical research; (4) discuss strategies to accelerate anticancer device development; and (5) provide transparency via a public forum regarding the regulatory challenges of developing products for management of patients with localized prostate cancer.

II. Topics for Discussion at the Public Workshop

The following topics will be discussed at this workshop:

- Regulatory issues in partial gland ablation for prostate cancer;
- overview of technology and consensus reports;
- the use of imaging and biopsy for patient selection and treatment targeting; and
- the design of clinical trials to measure cancer-specific and patient-centered outcomes.

The workshop will consist of formal presentations examining these regulatory, scientific and clinical topics, followed by panel discussion. During panel discussion, there will also be the opportunity for public participation and input.

Dated: May 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-11897 Filed 5-13-15; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-1211]

Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is

announcing the availability of a draft document entitled “Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Draft Guidance for Industry.” The draft guidance document provides blood establishments that collect blood or blood components, including Source Plasma, with revised donor deferral recommendations for individuals at increased risk for transmitting human immunodeficiency virus (HIV) infection. The draft guidance document recommends corresponding revisions to donor education materials, donor history questionnaires and accompanying materials, along with revisions to donor requalification and product management procedures. The document also incorporates certain other recommendations related to donor education materials and testing contained in the memorandum to blood establishments entitled, “Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products,” dated April 23, 1992 (1992 blood memo). The draft guidance, when finalized, is intended to supersede the 1992 blood memo.

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 July 14, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. 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 240-402-7800. 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: Valerie A. Butler, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301,

Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled “Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Draft Guidance for Industry.” The emergence of Acquired Immune Deficiency Syndrome (AIDS) in the early 1980s and the recognition that it could be transmitted by blood and blood products had profound effects on the U.S. blood system. Although initially identified in men who have sex with men (MSM) and associated with male-to-male sexual contact, AIDS was soon noted to be potentially transmitted by transfusion of blood components, and by infusion of clotting factor concentrates in individuals with hemophilia. Beginning in 1983, the FDA, issued recommendations for providing donors with education material on risk factors for AIDS and for deferring donors with such risk factors in an effort to prevent transmission of AIDS (later understood to be caused by HIV) by blood and blood products.

Since September 1985, FDA has recommended that blood establishments indefinitely defer male donors who have had sex with another male, even one time, since 1977, due to the strong clustering of AIDS illness in the MSM community and the subsequent discovery of high rates of HIV infection in that population. On April 23, 1992, FDA issued the 1992 blood memo, which contains the current recommendations regarding the deferral for MSM, as well as the deferral recommendations for other persons with behaviors associated with high rates of HIV exposure, namely commercial sex workers, intravenous drug users, and certain other individuals with other risk factors.

The use of donor education material, specific deferral questions and advances in HIV donor testing have reduced the risk of HIV transmission from blood transfusion from about 1 in 2500 units prior to HIV testing to a current estimated residual risk of about 1 in 1.47 million transfusions. During the period from 1997 to 2014, FDA and the Department of Health and Human Services (HHS) held a number of public meetings, including scientific workshops and meetings of the Blood Products Advisory Committee and the HHS Advisory Committee on Blood Safety and Availability to further review evidence and discuss FDA’s blood donor deferral policies to reduce the

risk of transmission of HIV by blood and blood products. Studies that might support a policy change were carried out by the Public Health Service agencies in 2011–2014. A policy change to the blood donor deferral period for MSM from indefinite deferral to 1 year since the last sexual contact was announced by the FDA Commissioner in December 2014. The draft guidance, when finalized, will implement that policy change.

In addition to providing donor deferral recommendations for individuals at increased risk for transmitting HIV infection, the draft guidance document incorporates certain recommendations contained in the 1992 blood memo. Certain other recommendations from the 1992 blood memo have not been included in the draft guidance document because they have become outdated over time, superseded by subsequent regulations or guidance documents, or have been incorporated into other guidance documents. However, to ensure that the final guidance document provides comprehensive recommendations for reducing the risk of HIV transmission by blood and blood products, we invite comments on the recommendations contained in the 1992 blood memo that have not been included in the draft guidance. Further, the draft guidance does not provide a specific list of recommended signs and symptoms associated with HIV for inclusion in the donor education materials. We invite comments and the submission of data on what specific signs and symptoms associated with HIV infection would be most appropriate for inclusion in education material in the blood donor setting. The draft guidance, when finalized, is intended to supersede the 1992 blood memo.

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 the current thinking of FDA on “Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements 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 601.12 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 606.171 have been approved under OMB control number 0910–0458; and the collections of information in 21 CFR 610.46, 630.6, 640.3 and 640.63 have been approved under OMB control number 0910–0116.

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: May 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11690 Filed 5–14–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0487]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Generic Clearance for the Collection of Qualitative Feedback on Food and Drug Administration Service Delivery

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, “Generic Clearance for the Collection of Qualitative Feedback on Food and Drug

Administration Service Delivery” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On September 24, 2014, the Agency submitted a proposed collection of information entitled, “Generic Clearance for the Collection of Qualitative Feedback on Food and Drug Administration Service Delivery” to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0697. The approval expires on November 30, 2017. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: May 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11689 Filed 5–14–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

U.S. National Authority for the WHO Global Code of Practice on the International Recruitment of Health Personnel; Notice of Public Meeting

Time and date: Meeting will be held on June 10th, 2015, 10:00 a.m. to 12:00 p.m. EDT.

Place: Room 405A, U.S. Department of Health & Human Services, 200 Independence Ave. SW., Washington, DC 20201.

Status: Open, but requiring RSVP to us.who.irhp@hhs.gov by June 3rd, 2015.

Purpose: The purpose of the World Health Organization (WHO) Global Code of Practice on International Recruitment of Health Personnel (Global Code) is “to establish and promote voluntary principles and practices for the ethical international recruitment of health personnel and to facilitate the strengthening of health systems.” The United States Government has designated the Office of Global Affairs (OGA) and the Health Resources and Services Administration (HRSA) as co-National Authority to be the point of contact for implementation activities. The Global Code encourages WHO member states to cooperate with all relevant stakeholders in their implementation efforts.

This meeting is thus intended to provide an update to all interested stakeholders on U.S. Global Code implementation efforts to date and to provide a forum for questions on activities related to implementation of the Global Code.

The meeting will be open to the public as indicated above, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify within their RSVP at least 10 business days prior to the meeting. Foreign nationals planning to attend the session in person will require additional paperwork for security clearance and that this clearance process requires a minimum of 10 business days.

RSVP: Due to security restrictions for entry into the HHS Humphrey Federal Building, we will need to receive RSVPs for this event. Please send your full name and organization to us.who.irhp@hhs.gov. If you are *not* a U.S. citizen, you must RSVP no later than May 26th, 2015. Please note this in the subject line of your RSVP, and our office will contact you to gain additional biographical information for your clearance. For U.S. citizens, please RSVP no later than Friday, June 3rd, 2015. Written comments are welcome and encouraged, even if you are planning to attend in person. Please send these to the email address: us.who.irhp@hhs.gov.

Dated: May 7, 2015.

Jimmy Kolker,

Assistant Secretary for Global Affairs, Department of Health and Human Services.

[FR Doc. 2015–11785 Filed 5–14–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Collaborative Applications: Behavioral Genetics and Epidemiology.

Date: June 2–3, 2015.

Time: 8:30 a.m. to 5:00 p.m.