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]

BILLING CODE 4164–01–P

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]

BILLING CODE 4164–01–P

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