The SA will notify the RO at least 60 days prior to the end of the rehabilitation hospital's/unit's cost reporting period of the IRF's compliance or non-compliance with the payment requirements. The information collected on these forms, along with other information submitted by the IRF is necessary for determining exclusion from the IPPS. Hospitals and units that have already been excluded need not reapply for exclusion. These facilities will automatically be reevaluated yearly to determine whether they continue to meet the exclusion criteria.

Form Number: CMS–437A and CMS–437B (OMB Control Number: 0938–0986); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits); *Number of Respondents:* 478; *Total Annual Responses:* 478; *Total Annual Hours:* 120. (For policy questions regarding this collection contact James Cowher at 410–786–1948).

Dated: May 12, 2015.

William N. Parham, III

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–11798 Filed 5–14–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1484]

Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators.'' The purpose of this guidance is to assist sponsor-investigators in preparing and submitting complete investigational new drug applications (INDs) to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) at FDA. Although not an exhaustive step-by-step instruction manual, this guidance highlights certain elements of this process to facilitate a sponsor-investigator's successful submission of an IND. This guidance also discusses the IND review process and general responsibilities of sponsor-investigators related to clinical investigations. Details of the informational content of an IND as well as information needed to complete required forms also are provided throughout this guidance.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 14, 2015.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 Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research, 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 that office in processing your requests. 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: Amalia Himaya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6439, Silver Spring, MD 20993–0002, 301–796–0700; or Stephen Ripley, 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 guidance for industry entitled ''Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators.'' The purpose of this guidance is to assist investigators in preparing and submitting complete INDs to CDER and CBER at FDA. Sponsor-investigators seeking to do clinical research often do not have the regulatory knowledge or the resources to hire experts to help them with the IND submission process. Although not an exhaustive step-by-step instruction manual, this guidance highlights certain elements of this process to facilitate a sponsor-investigator's successful submission of an IND. This guidance also discusses the IND review process and general responsibilities of sponsor-investigators related to clinical investigations. The guidance does not include discussions of all of the requirements that apply to the IND submission and review process or to conducting clinical research.

This guidance is directed primarily at those sponsor-investigators who are seeking to evaluate a drug that is either currently approved or is being investigated under an existing IND for a different indication. This guidance is not intended for sponsor-investigators who are developing a drug for commercial purposes (*i.e.,* seeking market approval or licensure). This guidance does not apply to clinical trials that do not need to be conducted under an IND (*i.e.,* that qualify for an IND exemption). The guidance also is not intended to address expanded access INDs or biologic devices.

This 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 INDs prepared and submitted by sponsor-investigators. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 312 have been approved under OMB control number 0910–0014.

III. Comments

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 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