• the statement ''Not for resale,'' and, if the repackaged radiopharmaceutical is distributed by an outsourcing facility other than pursuant to a prescription for an individual identified patient, the statement ''Office Use Only''; and

• a list of the active and inactive ingredients, unless such information is included on the label for the container from which the individual units are removed, as described in this document.

Another condition in the draft guidance is that the label on the container from which the individual units are removed for administration (secondary packaging, *e.g.,* the bag, box, or other package in which the repackaged products are distributed) includes the active and inactive ingredients, if the immediate product label is too small to include this information, and directions for use, including, as appropriate, dosage and administration, and the following information to facilitate adverse event reporting: *http://www.fda.gov/medwatch* and 1–800–FDA–1088.

We estimate that annually a total of approximately 2 outsourcing facilities (''No. of Respondents'' in table 1, row 1) will each design, test, and produce approximately 5 different labels (''No. of Disclosures per Respondent'' in table 1, row 1) for a total of 10 labels that include the information described previously (including directions for use) (''Total Annual Disclosures'' in table 1, row 1). We also estimate that designing, testing, and producing each label will take approximately 0.5 hours for each repackaged radiopharmaceutical (''Average Burden Hours per Disclosure'' in table 1, row 1). The provision to add the statement *http://www.fda.gov/medwatch* and 1–800–FDA–1088 is not included in this burden estimate because it is not considered a collection of information under the PRA because the information is ''originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

The draft guidance also references registration, adverse event reporting, product reporting, and current good manufacturing practices (CGMP) requirements for outsourcing facilities. The collection of information for outsourcing facility registration has been approved by the Office of Management and Budget (OMB) under OMB control number 0910–0777 (79 FR 69859, November 24, 2014). The collection of information for adverse event reporting by outsourcing facilities has been approved by OMB under OMB control number 0910–0800 (80 FR 60917, October 8, 2015). In the **Federal Register** of August 1, 2016 (81 FR 50523), FDA estimated the burden resulting from outsourcing facility electronic drug product reporting. In the **Federal Register** of July 2, 2014 (79 FR 37743), FDA estimated the burden resulting from outsourcing facility compliance with CGMP requirements.

The total estimated third-party disclosure burden resulting from the draft guidance is as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

Repackaging by outsourcing facilities	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Designing, testing, and producing each label on immediate containers, packages and/or outer containers.	2	5	10	.5 (30 minutes)	5

There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Electronic Access

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

Dated: December 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31512 Filed 12–28–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Identification and Characterization of the Infectious Disease Risks of Human Cells, Tissues, and Cellular and Tissue-Based Products; 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 ''Identification and Characterization of the Infectious Disease Risks of Human Cells, Tissues, and Cellular and Tissue-based Products.'' The purpose of the public workshop is to have a scientific discussion of the current methods available for identifying and characterizing infectious disease risks associated with human cells, tissues, and cellular and tissue-based products (HCT/Ps).

DATES: The public workshop will be held on February 8, 2017, from 8:30 a.m. to 4:30 p.m., and February 9, 2017, from 8:30 a.m. to 12:30 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the Wiley Auditorium located in the Harvey H. Wiley Federal Building, 5100 Campus Dr., College Park, MD 20740.

FOR FURTHER INFORMATION CONTACT: Monica Kapoor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3111C, Silver Spring, MD 20993, *CBERPublicEvents@fda.hhs.gov;* or Stacey Rivette, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 71, Rm. 3109B, Silver Spring, MD 20993, *CBERPublicEvents@fda.hhs.gov* with the subject line titled ''HCT/P Workshop.''

SUPPLEMENTARY INFORMATION:

I. Background

Transplantation of HCT/Ps represents an area of medicine important for saving and/or enhancing the lives of millions of individuals every year. In order to assure the safety of patients receiving HCT/P transplants, FDA issued regulations to prevent the introduction, transmission, or spread of communicable diseases by HCT/Ps under part 1271 (21 CFR part 1271) (May 25, 2004; 69 FR 29786). These regulations became effective on May 25, 2005. The regulations under part 1271, subpart C, contain the requirements for

tissue establishments for determining HCT/P donor eligibility. These requirements include the need to screen and test potential donors of HCT/Ps for relevant communicable disease agents and diseases (RCDADs).

The regulations under part 1271, subpart C, list the following RCDADs for all cells and tissues: Human immunodeficiency virus, types 1 and 2; hepatitis B virus; hepatitis C virus; human transmissible spongiform encephalopathy; and *Treponema pallidum.* These regulations also list human T-lymphotropic virus type I and type II as RCDADs for viable, leukocyte-rich cells and tissues. For reproductive cells or tissues, a disease agent or disease of the genitourinary tract includes *Chlamydia trachomatis* and *Neisseria gonorrhea.* In addition, the regulations under part 1271, subpart C, recognize that over time as new infectious diseases emerge there would be the need to designate additional RCDADs. The regulations describe the criteria for identifying new RCDADs. These criteria include that the disease or disease agent is potentially transmissible by a HCT/P: Either it has sufficient incidence and/or prevalence to affect the donor population; or if it were released in a manner to place potential donors at risk that it could be fatal or life-threatening, and that there were appropriate screening and legally marketed screening tests available for it. However, the regulations under part 1271, subpart C, do not specify the deliberative and scientific processes necessary to apply the criteria.

This workshop will describe currently available scientific methods to characterize both epidemiologic and biological features of emerging diseases and disease agents, and discuss their potential use in evaluating HCT/P infectious diseases risks for the purpose of identifying new RCDADs for the purposes of the HCT/P regulatory framework. Assessing the overall risk of a particular disease agent or disease to recipients of HCT/Ps requires consideration of multiple factors, including the presence of the disease agent or disease in the HCT/P donor population, potential for transmission by an HCT/P, and the potential morbidity or mortality in the recipient. In many cases, information for one or more of these factors may be limited or incomplete.

II. Topics for Discussion at the Public Workshop

The workshop is intended as a scientific discussion regarding the current methods available to identify and characterize infectious disease risks related to HCT/Ps. Topics discussed will include: (1) Estimating disease incidence and/or prevalence in the potential HCT/P donor population, (2) assessing the potential transmissibility of a disease by HCT/Ps, and (3) understanding the capabilities of current screening and testing methodologies. The workshop will also include discussion on how available information can be used to characterize the overall infectious disease risks posed by HCT/Ps.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following Web site at *https://www.eventbrite.com/e/identification-and-characterization-of-hctp-infectious-disease-risks-public-workshop-registration-24465329459.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by February 6, 2017. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation once they have been accepted. Attendance for this workshop is in-person only. FDA will post the agenda approximately 5 days before the workshop at *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm490175.htm.*

If you need special accommodations because of disability, please contact Monica Kapoor or Stacey Rivette no later than 7 days in advance of the meeting by email at *CBERPublicEvents@fda.hhs.gov* with the subject line titled ''HCT/P Workshop.''

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the Internet at *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm525001.html.*

Dated: December 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0269]

Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a final guidance for industry entitled ''Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' This guidance sets forth FDA's policy concerning certain prescription requirements for compounding human drug products for identified individual patients under section 503A of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). It addresses compounding after the receipt of a prescription for an identified individual patient, compounding before the receipt of a prescription for an identified individual patient (anticipatory compounding), and compounding for office use.

DATES: Submit electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that