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Another condition in the draft guidance is that the label on the container from which the individual units are removed for administration (secondary packaging, e.g., the bag, box, or other package in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.

The draft guidance also references registration, adverse event reporting, product reporting, and current good manufacturing practices (CGMP) requirements for outsourcing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 0910–0787 (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 The total estimated third-party disclosure burden resulting from the draft guidance is as follows: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>
<thead>
<tr>
<th>Repackaging by outsourcing facilities</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Average burden per disclosure</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designing, testing, and producing each label on intermediate containers, packages and/or outer containers.</td>
<td>2</td>
<td>5</td>
<td>10</td>
<td>.5 (30 minutes) ....</td>
<td>5</td>
</tr>
</tbody>
</table>

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.


Leslie Kux,
Associate Commissioner for Policy.

FOR FURTHER INFORMATION CONTACT: Monica Kapoor, 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; 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 gonorrhoea. 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 diseases 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.