agent does not raise new clinical safety concerns with respect to the HCT/P; and

- Either:

○ The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function, or

○ The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and is for the following uses:

- Autologous,
- Allogeneic, in a first-degree or second-degree blood relative, or
- Reproductive.

If an HCT/P does not meet all of the criteria set out under § 1271.10(a), the HCT/P will be regulated as a drug, device, and/or biological product under the Federal Food, Drug, and Cosmetic Act, and/or section 351 of the PHS Act (42 U.S.C. 262).

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement 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The draft guidance refers to previously approved collections of information found in FDA regulations.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 part 1271 have been approved under OMB control number 0910–0543.

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The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time.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Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or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.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm,* or *http://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.* Persons unable to download an electronic copy of the draft guidance entitled ''Minimal Manipulation of Human Cells, Tissues, and Cellular- and Tissue-Based Products; Draft Guidance for Industry and FDA Staff'' may send an email request to *CDRH-guidance@fda.hhs.gov* to receive an electronic copy of the document.

Dated: December 17, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30011 Filed 12–22–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0268]

Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration: Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration.'' The document provides guidance to industry on how to label bottled or otherwise packaged beers that are subject to FDA's labeling laws and regulations. This guidance is being issued in light of the ruling by the Alcohol and Tobacco Tax and Trade Bureau (TTB) (formerly the Bureau of Alcohol, Tobacco, and Firearms) (TTB Ruling 2008–3, dated July 7, 2008) clarifying that certain beers do not meet the definition of a ''malt beverage'' under the Federal Alcohol Administration Act (FAA Act). Because these beers are not subject to the labeling provisions of the FAA Act, they are subject to the labeling provisions of the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act.

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

ADDRESSES: Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the guidance to the Office of Nutrition, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 17, 2009 (74 FR 41438), we announced the availability of a draft guidance entitled ''Guidance for Industry; Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request'' and gave interested parties an opportunity to submit comments on the draft guidance at any time and comments on the proposed collection of information by October 16, 2009. We received one comment which we reviewed and evaluated. On our own initiative, we added a reference to the nutrition labeling requirements for certain beers and other alcohol beverages served in restaurants or similar retail food establishments, under FDA's final rule for menu labeling which appeared in the **Federal Register** on December 1, 2014 (79 FR 71156). We also clarified that the guidance pertains to bottled or otherwise packaged beers subject to our jurisdiction. We are issuing the guidance with no substantive changes.

The final guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents our current thinking on the labeling of certain

bottled or otherwise packaged beers subject to our jurisdiction. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions 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 collection of information in this guidance was approved under OMB control number 0910–0728.

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 guidance at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Always access an FDA guidance document using FDA's Web site listed previously to find the most current version of the guidance.

V. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified all the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.**)

1. TTB Ruling 2008–3, July 7, 2008, available at: *http://www.ttb.gov/rulings/2008–3.pdf.*

2. Memorandum of Understanding 225–88–2000 between FDA and Bureau of Alcohol, Tobacco and Firearms, available at: *http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116370.htm.*

Dated: *December 17, 2014.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29988 Filed 12–22–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; NIMH Data Repositories Data Submission Request; NIMH Data Repositories Data Access and Use Certification

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on October 7, 2014, page 60479 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Mental Health (NIMH), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

DATES: *Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Rockville Pike, Bethesda, MD 20892, or call 301–443–4335 or Email your request, including your address to: *nimhprapubliccomments@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection

NIMH Data Repositories (NDR) Data Submission Request—Revision 0925–0667; the NIMH Data Repositories Data Access and Use Certification—National Institute of Mental Health (NIMH), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Institutes of Mental Health (NIMH) Data Repositories are a group of Federal data repositories based on an informatics platform for human-subjects research domains related to mental health, initially established as the National Database for Autism Research (NDAR) to support autism-related research. In 2013, NIMH received approval from OMB for use of the NIMH Data Access Request and Use Certification (DUC) Form to meet the unique data access needs of all existing NIMH data repositories, which at the time consisted of NDAR, Pediatric MRI (PedsMRI), and the NIMH Clinical Research Datasets (NCRD)—OMB# 0925–0667 (Expiration: 09/30/2016). Now in 2014, two new databases have been added and integrated into the NDAR infrastructure, NDCT and RDoCdb. At this time, NIMH is seeking OMB approval to add an all-purpose NIMH Data Repositories Data Submission Request Form and to revise the all-purpose NIMH Data Repositories Data Access and Use Certification Form. As the data repositories have matured, and with the introduction of the new databases—namely NDCT and RDoCdb—the information being collected for data submission has become more complex, rendering an OMB-approved submission form a new necessity.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 221.