Blended Seafood Products, which provides guidance for our staff on labeling requirements for processed and blended seafood products made primarily with fish protein. The CPG has been revised for clarity and format, including the addition of Regulatory Action Guidance and Specimen Charges sections. The CPG contains information that may be useful to the regulated industry and to the public.

II. Comments

Interested persons may submit either written comments regarding the guidance to the Division of Dockets Management (see **ADDRESSES**) or electronic comments regarding the guidance to *http://www.regulations.gov.* 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.*

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: December 18, 2014.

Melinda K. Plaisir,

Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs.

[FR Doc. 2014–30015 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–2014–D–1696]

Minimal Manipulation of Human Cells, Tissues, and Cellular- and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Minimal Manipulation of Human Cells, Tissues, and Cellular- and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff.'' The draft guidance document provides human cells, tissues, and cellular- and tissue-based product (HCT/P) manufacturers, healthcare providers, and FDA staff with recommendations for meeting the criterion of ''minimal manipulation'' as it applies to HCT/Ps. The draft guidance, when finalized, is intended to supersede the document entitled ''Guidance for Industry and FDA Staff: Minimal Manipulation of Structural Tissue Jurisdictional Update'' dated September 2006. This draft guidance is not final nor is it in effect at this time.

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 February 23, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002, or to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002, or you may send an email request to the Office of Combination Products (OCP) at *combination@fda.gov.* If you are submitting a written request, send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. 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: Melissa Segal, 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, or Angela Krueger, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1666, Silver Spring, MD 20993–0002, 301–796–6380, or Leigh Hayes, Office of Combination Products, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Hub 5129, Silver Spring, MD 20993–0002, 301–796–8938.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Minimal Manipulation of Human Cells, Tissues, and Cellular- and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff.'' The draft guidance document provides HCT/P manufacturers, healthcare providers, and FDA staff with recommendations for meeting the 21 CFR 1271.10(a)(1) criterion of minimal manipulation. The draft guidance, when finalized, is intended to supersede the document entitled ''Guidance for Industry and FDA Staff: Minimal Manipulation of Structural Tissue Jurisdictional Update'' dated September 2006. Note that FDA intends to publish a separate draft guidance document on the criterion described in § 1271.10(a)(2), the HCT/P is intended for homologous use only as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent.

HCT/Ps are defined in § 1271.3(d) as articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. FDA has implemented a risk-based approach to the regulation of HCT/Ps. Under the authority of section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264), FDA established regulations for all HCT/Ps to prevent the introduction, transmission, and spread of communicable diseases. These regulations can be found in part 1271. HCT/Ps are regulated solely under section 361 of the PHS Act and part 1271, if they meet all of the following criteria (21 CFR 1271.10(a)):

- The HCT/P is minimally manipulated;
- The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;
- The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage

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