can find and read the electronic form of all comments received into any FAA dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Theodora Kessaris, New Program Implementation and Technical Support Branch, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8166; facsimile: 202–267–5229; email: *Theodora.kessaris@faa.gov.*

Background

On October 22, 2014, the FAA published a proposed a new chapter of FAA Order 8900.1 and a proposed new AC related to Aircraft Dispatcher Certification Courses. The new chapter in FAA Order 8900.1 chapter establishes Policy not previously addressed in FAA Orders or ACs. The associated AC, 65–XX, provides guidelines to operators and potential operators of Aircraft Dispatcher Certification Courses. On November 06, 2014, Sheffield School of Aeronautics placed a comment in this docket requesting the publication of additional supporting documents which contain policy related to Designated Aircraft Dispatcher Examiners (DADE). Additionally, Sheffield requested the FAA consider extending the comment period, which is scheduled to close on December 22, 2014. In response to these requests, we have extended the comment period for the Aircraft Dispatcher Certification Course Policy contained in this docket for another 60 days to allow additional review by industry stakeholders. We have also made the DADE policy supporting documents available for review only, in their own respective docket, which is FAA–2011–1149. That particular docket, which is not open for comment, can be accessed at the following URL: *http://www.regulations.gov/#!docketDetail;D=FAA-2011-1149.*

The FAA does not anticipate any further extension of the comment period for the draft policy related to Aircraft Dispatcher Certification Courses, contained in this docket.

The agency will consider all comments received by February 22, 2015. Comments received after that date may be considered if consideration will not delay agency action on the review. A copy of the proposed order and AC is available for review in the assigned docket for the Order at *http://www.regulations.gov.*

Issued in Washington, DC, on December 15, 2014.

John Barbagallo,

Deputy Director, FAA Flight Standards Service.

[FR Doc. 2014–30221 Filed 12–23–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. FDA–2014–D–1856]

Human Cells, Tissues, and Cellular and Tissue-Based Products From Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments on draft guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) from Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry'' dated December 2014. The draft guidance document provides sponsors, clinicians, and other establishments that manufacture and use adipose tissue, with recommendations for complying with the regulatory framework for HCT/Ps. For purposes of applying the HCT/P regulatory framework, FDA considers connective tissue, including adipose tissue, to be a structural tissue. 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 at *combination@fda.gov.* If you are submitting a written request, send one self-addressed adhesive label to assist that office in processing your request. 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: Lori J. Churchyard, 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, Rm. 5127, Silver Spring, MD 20993–0002, email: *combination@fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) from Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry'' dated December 2014. FDA has recently received numerous inquiries regarding HCT/Ps from adipose tissues. This draft guidance document provides sponsors, clinicians, and other establishments that manufacture and use HCT/Ps from adipose tissue with the Agency's current

thinking with respect to regulatory considerations for adipose tissue.

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 21 CFR 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 ''Human Cells, Tissues, and Cellular and Tissue-Based Products from Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry,'' may send an email request to *CDRH-guidance@fda.hhs.gov* to receive an electronic copy of the document.

Dated: December 18, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30142 Filed 12–23–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2014–1001]

RIN 1625–AA00

Safety Zones; Annual Events Requiring Safety Zones in the Captain of the Port Lake Michigan Zone

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend its safety zones regulations for Annual Events in the Captain of the Port Lake Michigan zone. This proposed amendment updates 18 permanent safety zones, adds 5 new permanent safety zones, and reformats the coordinates for safety zones. These amendments and additions are necessary to protect spectators, participants, and vessels from the hazards associated with annual maritime events, including fireworks displays, boat races, and air shows, and improves the precision and compatibility of safety zone coordinates.

DATES: Comments and related material must be received by the Coast Guard on or before January 23, 2015.

ADDRESSES: You may submit comments identified by docket number USCG–2014–1001 using any one of the following methods:

(1) Federal eRulemaking Portal: *http://www.regulations.gov.*

(2) Fax: 202–493–2251.

(3) Mail: Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(4) Delivery: Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments. To avoid duplication, please use only one of these four methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Petty Officer Joseph McCollum, U.S. Coast Guard Sector Lake Michigan; telephone 414–747–7148, email *Joseph.P.McCollum@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR **Federal Register**
NPRM Notice of Proposed Rulemaking

A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2014–1001), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at *http://www.regulations.gov* or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* click on the ''submit a comment'' box, which will then become highlighted in blue. In the ''Document Type'' drop down menu select ''Proposed Rule'' and insert ''USCG–2014–1001'' in the ''Keyword'' box. Click ''Search'' then click on the balloon shape in the ''Actions'' column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and