the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 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.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 23, 2014 (79 FR 77012), FDA announced 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of a draft document entitled ''Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff'' dated December 2014. The draft guidance document provides human cells, tissues, and cellular and tissue-based product (HCT/P) manufacturers, health care providers, and FDA staff with recommendations for meeting the 21 CFR 1271.10(a)(1) criterion of minimal manipulation. Interested persons were originally given until February 23, 2015, to comment on the draft guidance.

Elsewhere in this issue of the **Federal Register**, FDA is announcing four other related documents. In a separate document, FDA is announcing a public hearing entitled ''Draft Guidances Relating to the Regulation of Human Cells, Tissues, or Cellular or Tissue-Based Products; Public Hearing; Request for Comments'' (part 15 hearing) to be held on April 13, 2016, to provide stakeholders with the opportunity to discuss FDA's policy on regulation of HCT/Ps related to the four draft guidances on the following topics: Homologous use, same surgical procedure exception, minimal manipulation, and adipose tissue.

In a separate document, FDA is announcing the availability of a draft document entitled ''Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and FDA Staff.''

In separate documents, FDA is also reopening the comment periods to FDA's public dockets on the previously issued draft guidance documents on the following topics related to HCT/Ps: Adipose tissue (Docket No. FDA–2014–D–1856) and same surgical procedure exception (Docket No. FDA–2014–D–1584).

II. Reopening of Comment Period

Following publication of December 23, 2014, notice of availability, FDA received a request to allow interested persons additional time to comment. In conjunction with the part 15 hearing and announcement of availability of the homologous use draft guidance, FDA is reopening the comment period to allow potential respondents to thoroughly evaluate and address pertinent issues. The minimal manipulation draft guidance and other related guidances (homologous use, same surgical procedure exception, adipose tissue) all deal with the interpretation of the regulations under 21 CFR part 1271 that will be addressed as part of the part 15 hearing.

Dated: October 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27705 Filed 10–29–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. FDA–2015–D–3719]

Draft Guidances Relating to the Regulation of Human Cells, Tissues, or Cellular or Tissue-Based Products; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a 1-day public hearing to obtain input on four recently issued draft guidances relating to the regulation of human cells, tissues, or cellular or tissue-based products (HCT/Ps). These draft guidances were issued by FDA in response to stakeholders' requests for guidance on FDA's current views about how manufacturers, establishments, and distributors of HCT/Ps and health care professionals can meet the criteria under the Agency's regulations that apply to HCT/Ps. FDA will consider information it obtains from the public hearing in the finalization of these guidances.

DATES: The public hearing will be held on April 13, 2016, from 8 a.m. to 5 p.m. The meeting may be extended or end early depending on the level of public participation. Persons seeking to attend or to present at the public hearing must register by January 8, 2016. Section IV provides attendance and registration information. Electronic or written comments will be accepted after the public hearing until April 29, 2016.

ADDRESSES: The public hearing will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public hearing participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/aboutfda/workingatfda/buildingsandfacilities/whiteoakcampusinformation/ucm241740.htm.*

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–3719 for ''Draft Guidances Relating to the Regulation of Human Cells, Tissues, or Cellular or Tissue-Based Products; Public Hearing; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

A link to the live Webcast of this public hearing will be available at *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm462125.htm* on the day of the public hearing. A video record of the public hearing will be available at *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm462125.htm.* A video record of the public hearing will be available at the same Web site address for 1 year.

FOR FURTHER INFORMATION CONTACT: Lori Jo Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911, *lori.olsenchurchyard@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

HCT/Ps are defined in § 1271.3(d) (21 CFR 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. An HCT/P is regulated solely under section 361 of the PHS Act and part 1271, if it meets all of the following criteria (§ 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 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 forth 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).

In certain circumstances as provided in § 1271.15, an establishment that manufactures HCT/Ps may be excepted from the requirements in part 1271. For example, an establishment is excepted from the requirements if it ''removes HCT/Ps from an individual and implants such HCT/Ps into the same individual during the same surgical procedure'' (§ 1271.15(b)).

II. Draft Guidances

As part of its commitment to public outreach and to explain the Agency's current thinking on the regulatory framework for HCT/Ps, FDA has issued the following four draft guidances:

• Same Surgical Procedure Exception under § 1271.15(b): Questions and Answers Regarding the Scope of the Exception; Draft Guidance for Industry (Same Surgical Procedure Exception Draft Guidance);

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

• Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) from Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry (Adipose Tissue Draft Guidance); and

• Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff (Homologous Use Draft Guidance).

The Same Surgical Procedure Exception Draft Guidance was published in the **Federal Register** of October 23, 2014 (79 FR 63348), and provides answers to common questions regarding the scope of the exception.

The Minimal Manipulation Draft Guidance was published in the 03'**Federal Register** of December 23, 2014 (79 FR 77012), and provides recommendations for meeting the § 1271.10(a)(1) criterion of minimal manipulation.

The Adipose Tissue Draft Guidance was published in the **Federal Register** of December 24, 2014 (79 FR 77414), and

provides those who manufacture and use adipose tissue with recommendations for complying with the regulatory framework for HCT/Ps.

Elsewhere in this issue of the **Federal Register,** FDA is announcing the availability of the Homologous Use Draft Guidance which provides recommendations for applying the § 1271.10(a)(2) homologous use criterion, and is also announcing the reopening of the comment periods on the Same Surgical Procedure Exception, Minimal Manipulation, and Adipose Tissue Draft Guidances.

III. Purpose and Scope of the Public Hearing

The purpose of this public hearing is to obtain comments on these four draft guidances. FDA is seeking feedback, both general and specific, from a broad group of stakeholders, including HCT/P manufacturers, tissue establishments, biological and device product manufacturers, health care professionals, clinicians, biomedical researchers, and the public. For example, FDA would like comments on the scope of each guidance, including the particular topics covered, the particular questions posed, whether there are additional issues for which they seek guidance, and whether FDA's recommendations for each topic are sufficiently clear and consistent within and across documents to provide meaningful guidance to stakeholders. In addition, FDA welcomes any comments that will enhance the usefulness and clarity of these documents.

FDA recommends that comments exclude discussion of products which do not meet the definition of an HCT/P, such as platelet rich plasma. FDA also recommends that stakeholders coordinate comments when possible in order to allow for presentation of a wide range of perspectives within the allotted time of the meeting.

IV. Attendance and Registration

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance is free and will be on a first-come, first-served basis. Individuals who wish to present at the public hearing must register by sending an email to *CBERPublicEvents@fda.hhs.gov* on or before January 8, 2016, and provide complete contact information, including name, title, affiliation, address, email, and phone number. Those without email access may register by contacting Sherri Revell or Loni Warren Henderson at 240–402–7800. You should identify each guidance you wish to comment on in your presentation so that FDA can consider that information in organizing the presentations. Individuals and organizations with common interests should consolidate or coordinate their presentations and request time for a joint presentation. FDA will do its best to accommodate requests to speak and will determine the amount of time allotted for each oral presentation, and the approximate time that each oral presentation is scheduled to begin. FDA will notify registered presenters of their scheduled times, and make available an agenda at *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm462125.htm* on or before February 5, 2016. Once FDA notifies registered presenters of their scheduled times, presenters should submit an electronic copy of their presentation to *CBERPublicEvents@fda.hhs.gov* by March 11, 2016.

If you need special accommodations because of a disability, please contact Sherri Revell or Loni Warren Henderson at 240–402–7800 at least 7 days before the meeting.

A link to the live Web cast of this public hearing will be available at *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm462125.htm* on the day of the public hearing. A video record of the public hearing will be available at *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm462125.htm* following the meeting. A video record of the public hearing will be available at the same Web site address for 1 year.

V. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, accompanied by FDA senior management from the Office of the Commissioner and the Center for Biologics Evaluation and Research.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C). Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see section VI). To the extent that the conditions for the hearing, as described in this document, conflict with any provisions set out in part 15, this document acts as a waiver of those provisions as specified in § 15.30(h).

VI. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *www.regulations.gov* and *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm462125.htm*. It may be viewed at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.*

Dated: October 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27703 Filed 10–29–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. FDA–2014–D–1584]

Same Surgical Procedure Exception: Questions and Answers Regarding the Scope of the Exception; Draft Guidance for Industry; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the draft document entitled ''Same Surgical Procedure Exception: Questions and Answers Regarding the Scope of the Exception; Draft Guidance for Industry'' announced in the **Federal Register** of October 23, 2014. FDA is reopening the comment period to allow interested persons