Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception.'' The guidance provides tissue establishments and health care professionals with FDA's current thinking on the scope of the exception set forth in part 1271 (21 CFR part 1271), specifically the exception set forth in § 1271.15(b) (21 CFR 1271.15(b)). This guidance does not address the other exceptions in § 1271.15. The guidance, presented in question and answer format, provides FDA's current interpretation of this regulation and includes examples based on inquiries received by the Agency since the final rule entitled ''Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing'' published in the **Federal Register** of January 19, 2001 (66 FR 5447).

In the **Federal Register** of October 23, 2014 (79 FR 63348), FDA announced the availability of the draft guidance of the same title. Additionally, in the **Federal Register** of December 24, 2014 (79 FR 77414), FDA announced the availability of the draft guidance entitled ''Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) from Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry'' dated December 2014 (Adipose Draft Guidance).

In the **Federal Register** of October 30, 2015, FDA reopened the comment period for three HCT/P-related draft guidances (80 FR 66847, 66849, and 66844, respectively) and announced the availability of another HCT/P-related draft guidance (80 FR 66850). Comments on the four HCT/P-related guidances were requested by April 29, 2016. Lastly, in the **Federal Register** of October 30, 2015 (80 FR 66845), FDA announced a 1-day part 15 (21 CFR part 15) public hearing to obtain input on the four HCT/P-related guidances to be held on April 13, 2016.

Due to considerable interest in the public hearing and to give stakeholders additional time to provide comments to the Agency, on February 29, 2016, FDA announced that the hearing was postponed. In the **Federal Register** of April 22, 2016 (81 FR 23661 and 81 FR 23664, respectively), FDA announced the rescheduled part 15 hearing date of September 12 and 13, 2016, and an extension of the comment period from April 29, 2016, until September 27, 2016, on the four HCT/P-related guidances. Also in the **Federal Register** of April 22, 2016 (81 FR 23708), FDA announced a public workshop to be held on September 8, 2016, on the ''Scientific Evidence in Development of HCT/Ps Subject to Premarket Approval.''

FDA received numerous comments on the draft guidance and the Adipose Draft Guidance in response to the request for comments, and those comments were considered in developing the final guidance. The guidance announced in this notification finalizes the draft guidance of the same title dated October 2014. This guidance also finalizes certain material related to adipose tissue that was included in the Adipose Draft Guidance.

The material in this guidance related to adipose tissue, together with the material in the final guidance entitled ''Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff'' dated November 2017 (Minimal Manipulation and Homologous Use Guidance) related to adipose tissue, supersedes the Adipose Draft Guidance. Accordingly, FDA does not intend to finalize the Adipose Draft Guidance, which is now withdrawn.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the Minimal Manipulation and Homologous Use Guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

The 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. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov*.

Dated: November 13, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24839 Filed 11–16–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. FDA–2017–D–6146]

Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled ''Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff.'' The guidance provides human cells, tissues, and cellular and tissue-based product (HCT/P) manufacturers, healthcare providers, and FDA staff, with FDA's current thinking on the regulatory criteria of minimal manipulation and homologous use. The guidance is intended to improve stakeholders' understanding of the definitions of minimal manipulation and homologous use and how the regulatory criteria apply to their HCT/Ps. It also informs manufacturers, healthcare providers, and other interested persons that the Agency generally intends to exercise enforcement discretion over the next 36 months under limited conditions, with respect to the investigational new drug (IND) application and premarket approval (biologics license application (BLA)) requirements, for certain HCT/Ps.

DATES: The announcement of the guidance is published in the **Federal Register** on November 17, 2017.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2017–D–6146 for ''Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the 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 that office in processing your request. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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. 1676, 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. 5129, Silver Spring, MD 20993–0002, 301–796–8938.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Regulatory Considerations for Human Cells, Tissues, Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff.'' The guidance provides HCT/P manufacturers, healthcare providers, and FDA staff, with our current thinking on the criteria under part 1271 (21 CFR part 1271), specifically the § 1271.10(a)(1) (21 CFR 1271.10(a)(1)) criterion of minimal manipulation and the § 1271.10(a)(2) criterion of homologous use. The interpretation of the minimal manipulation and homologous use criteria and definitions of related key terms have been of considerable interest to industry stakeholders since the criteria and definitions were first proposed.[1] The guidance document is intended to improve stakeholders' understanding of the definitions of minimal manipulation in § 1271.3(f) and homologous use in § 1271.3(c). It will also facilitate stakeholders' understanding of how the regulatory criteria in § 1271.10(a)(1) and (2) apply to their HCT/Ps. The guidance document explains the regulatory scope of the regulations, as well as the Agency's compliance policy regarding certain regulatory requirements relating to HCT/Ps. In addition, the guidance document informs manufacturers, health care providers, and other interested persons that over the next 36 months, we intend to exercise enforcement discretion under limited

[1] ''Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products'' 63 FR 26744 at 26748–49 (May 14, 1998) *https://www.gpo.gov/fdsys/pkg/FR-1998-05-14/pdf/98-12751.pdf.*

conditions with respect to the IND application or premarket approval (BLA) requirements, for certain HCT/Ps.

In the **Federal Register** of December 23, 2014 (79 FR 77012), FDA announced the availability of the draft guidance 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 (Minimal Manipulation Draft Guidance), and in the **Federal Register** of December 24, 2014 (79 FR 77414), FDA announced the availability of draft guidance entitled ''Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) from Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry'' dated December 2014 (Adipose Draft Guidance). Additionally, in the **Federal Register** of October 30, 2015 (80 FR 66850), FDA announced the availability of the draft guidance entitled ''Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and FDA Staff'' dated October 2015 (Homologous Use Draft Guidance).

Also in the **Federal Register** of October 30, 2015, FDA reopened the comment period on the Minimal Manipulation Draft Guidance (80 FR 66844), Adipose Draft Guidance (80 FR 66849), and a third HCT/P-related guidance addressing the same surgical procedure exception in § 1271.15(b) (80 FR 66847) (Same Surgical Procedure Exception Draft Guidance). Comments on these three HCT/P-related guidances, as well as the Homologous Use Draft Guidance, were requested by April 29, 2016. Lastly, the **Federal Register** of October 30, 2015 (80 FR 66845), FDA announced a 1-day part 15 (21 CFR part 15) public hearing to obtain input on the four HCT/P-related guidances to be held on April 13, 2016.

Due to considerable interest in the public hearing and to give stakeholders additional time to provide comments to the Agency, on February 29, 2016, FDA announced that the hearing was postponed. In the **Federal Register** of April 22, 2016 (81 FR 23661 and 81 FR 23664, respectively), FDA announced the rescheduled part 15 hearing date of September 12 and 13, 2016, and an extension of the comment period from April 29, 2016, until September 27, 2016, on the four HCT/P-related guidances. Also in the **Federal Register** of April 22, 2016 (81 FR 23708), FDA announced a public workshop on the ''Scientific Evidence in Development of HCT/Ps Subject to Premarket Approval.''

FDA received numerous comments on the Minimal Manipulation Draft Guidance, Homologous Use Draft Guidance, and the Adipose Draft Guidance in response to the request for comments, and those comments were considered in developing the final guidance in this notification.

The guidance document announced in this notification finalizes the Minimal Manipulation Draft Guidance and the Homologous Use Draft Guidance. The guidance document also finalizes certain material related to adipose tissue that was included in the Adipose Draft Guidance. The material in this guidance document related to adipose tissue, together with the material related to adipose tissue included in the guidance finalizing the Same Surgical Procedure Exception Draft Guidance, the availability of which is announced elsewhere in this issue of the **Federal Register**, supersedes the Adipose Draft Guidance. Accordingly, FDA does not intend to finalize the Adipose Tissue Guidance, which is now withdrawn. Finally, this guidance supersedes the guidance entitled ''Minimal Manipulation of Structural Tissue (Jurisdictional Update) Guidance for Industry and FDA Staff'' dated September 2006.

FDA is also announcing via this **Federal Register** notification that, with the publication of this guidance document, it will cease posting the Tissue Reference Group (TRG) annual reports on FDA's Web site. The TRG was created as specified in the ''Proposed Approach to the Regulation of Cellular and Tissue-Based Products'' dated February 28, 1997 (March 4, 1997; 62 FR 9721). The purpose of the TRG is to provide a single reference point for product specific questions received by FDA (either through the Centers, or from the Office of Combination Products) concerning jurisdiction and applicable regulation of HCT/Ps.

In 1998, the TRG began publishing its recommendations in an annual report that was posted on FDA's Web site. Originally intended to assist industry in understanding the scientific rationale for the TRG recommendations, the recommendations are stated in general terms in order to protect proprietary information. As a result, FDA has received feedback from stakeholders that the annual reports do not provide helpful information. Therefore, we are announcing that although the TRG will continue to provide recommendations, the TRG annual reports will no longer be posted on FDA's Web site. We note that this final guidance is intended to help clarify the minimal manipulation and homologous use criteria in § 1271.10(a)(1) and (2), and thus addresses many of the questions that had been posed to the TRG.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

The 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. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm;* or *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm;* or *https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/default.htm;* or *https://www.regulations.gov.*

Dated: November 13, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 943

[SATS No. TX–067–FOR; Docket ID: OSM–2016–0001; S1D1S SS08011000 SX064A000 189S180110; S2D2S SS08011000 SX064A000 18XS501520]

Texas Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.