

public hearing must register at <https://www.eventbrite.com/e/part-15-hearing-on-draft-guidances-relating-to-the-regulation-of-hctps-registration-22921962206> on or before June 1, 2016. Persons who wish to attend and speak at the public hearing will be required to provide complete contact information, including name, title, affiliation, email, and phone number. To help FDA organize the presentations, persons who wish to attend and speak must also indicate whether they are speaking on their own behalf or on behalf of an organization. If speaking on behalf of an organization, the name of the organization must be provided. Persons who wish to attend and speak must also indicate if they will be speaking on the draft guidance documents. Individuals and organizations with common interests should consolidate or coordinate their presentations and request time for a joint presentation. There will be no open public session at the public hearing.

FDA will do its best to accommodate requests to speak at the public hearing and will determine the amount of time allotted for each oral presentation, and the approximate time that each oral presentation will be scheduled to begin. Multiple speakers from the same organization will be given one presentation slot for that organization. If the number of persons or organizations requesting to speak is greater than can be reasonably accommodated, FDA will close registration for speakers. FDA will notify registered speakers of their scheduled times, and make available an agenda at <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm462125.htm> on or before July 1, 2016. Once FDA notifies registered speakers of their scheduled times, presenters should submit an electronic copy of their presentation to [CBERPublicEvents@fda.hhs.gov](mailto:CBERPublicEvents@fda.hhs.gov) by August 1, 2016.

If you need special accommodations because of a disability, please contact Sherri Revell or Loni Warren Henderson at 240-402-8010 at least 7 days before the hearing.

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 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, who will be 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 § 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 of this document). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice 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](http://www.regulations.gov) and <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm462125.htm>. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). 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: April 19, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-09372 Filed 4-21-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 1271

[Docket Nos. FDA-2014-D-1584, FDA-2014-D-1696, FDA-2014-D-1856, and FDA-2015-D-3581]

#### Draft Guidances Relating to the Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products; Extension of Comment Periods

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification; extension of comment periods.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is extending the comment period for the draft guidance documents entitled "Same Surgical Procedure Exception: Questions and Answers Regarding the Scope of the Exception; Draft Guidance for Industry"; "Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff"; "Human Cells, Tissues, and Cellular and Tissue-Based Products from Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry"; and "Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and FDA Staff." The Agency is taking this action to allow interested persons additional time to submit comments and any new information.

**DATES:** FDA is extending the comment period on the four draft guidances announced in the **Federal Register** (see **SUPPLEMENTARY INFORMATION**). Submit either electronic or written comments by September 27, 2016.

**ADDRESSES:** 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-2014-D-1584 for "Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception; Draft Guidance for Industry"; Docket No. FDA-2014-D-1696 for "Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff"; Docket No. FDA-2014-D-1856 for "Human Cells, Tissues, and Cellular and Tissue-Based Products from Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry"; or Docket No. FDA-2015-D-3581 for "Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and FDA Staff." 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.

**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](mailto:lori.olsenchurchyard@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 23, 2014 (79 FR 63348), FDA announced the availability of a draft document entitled "Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception; Draft Guidance for Industry" dated October 2014.

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.

In the **Federal Register** of December 24, 2014 (79 FR 77414), FDA announced

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.

Following publication of these three notices of availability, FDA received requests to allow interested persons additional time to comment.

In the **Federal Register** of October 30, 2015 (80 FR 66850), FDA announced 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" dated October 2015.

In the **Federal Register** of October 30, 2015 (80 FR 66845), FDA announced a public hearing in a notice entitled "Draft Guidances Relating to the Regulation of Human Cells, Tissues, or Cellular or Tissue-Based Products; Public Hearing; Request for Comments".

The draft guidances on same surgical procedure, minimal manipulation, adipose tissue, and homologous use provide recommendations for complying with the regulatory framework for human cells, tissues, and cellular and tissue based products under 21 CFR part 1271 that were to be discussed during the part 15 (21 CFR part 15) hearing. In conjunction with the part 15 hearing and announcement of availability of the homologous use draft guidance, in the **Federal Register** of October 30, 2015 (80 FR 66847; 80 FR 66844; 80 FR 66849), FDA reopened the comment periods on the same surgical procedure, minimal manipulation, and adipose tissue draft guidances, respectively, to allow potential respondents time to thoroughly evaluate and address pertinent issues. Comments were requested by April 29, 2016. In this notice FDA is extending the comment period to September 27, 2016.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the rescheduling of a 2-day part 15 public hearing to September 12 and 13, 2016, to obtain input from stakeholders on the four issued draft guidance documents. In a separate document, FDA is also announcing a public scientific workshop to identify and discuss scientific considerations and challenges to help inform the development of human cells, tissues, and cellular and tissue-based products subject to premarket approval, including stem cell-based products.

Dated: April 19, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-09366 Filed 4-21-16; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R04-OAR-2015-0618; FRL-9945-21-Region 4]

#### Air Plan Approval: Tennessee: Knox County VOC Limits Revision for Permits

**AGENCY:** Environmental Protection Agency.

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve a portion of a State Implementation Plan (SIP) revision submitted by the State of Tennessee, submitted on March 14, 2014, through the Tennessee Department of Environmental Conservation on behalf of the Knox County Department of Air Quality Management (Knox County) to address changes to a Knox County regulation regarding permits. EPA is proposing to approve this SIP revision because the State has demonstrated that it is consistent with the Clean Air Act.

**DATES:** Written comments must be received on or before May 23, 2016.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R04-OAR-2015-0618 at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from [Regulations.gov](http://www.regulations.gov). EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit

<http://www2.epa.gov/dockets/commenting-epa-dockets>.

**FOR FURTHER INFORMATION CONTACT:** Zuri Farngalo or D. Brad Akers, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. Mr. Farngalo can be reached at (404) 562-9152 and via electronic mail at [farngalo.zuri@epa.gov](mailto:farngalo.zuri@epa.gov). Mr. Akers can be reached at (404) 562-9089 and via electronic mail at [akers.brad@epa.gov](mailto:akers.brad@epa.gov).

**SUPPLEMENTARY INFORMATION:** In the Rules and Regulations section of this issue of the **Federal Register**, EPA is approving the State's implementation plan revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

Dated: April 6, 2016.

**Heather McTeer Toney,**

*Regional Administrator, Region 4.*

[FR Doc. 2016-09160 Filed 4-21-16; 8:45 am]

**BILLING CODE 6560-50-P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

#### 43 CFR Part 1600

[LLWO210000.16X.L16100000.PN0000]

**RIN 1004-AE39**

#### Resource Management Planning

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Proposed rule; extension of public comment period.

**SUMMARY:** On February 25, 2016, the Bureau of Land Management (BLM) published in the **Federal Register** a proposed rule to amend existing regulations that establish the procedures used to prepare, revise, or amend land use plans pursuant to the Federal Land Policy and Management Act (FLPMA).

The proposed rule would enable the BLM to more readily address landscape-scale resource issues, such as wildfire, habitat connectivity, or the demand for renewable and non-renewable energy sources and to respond more effectively to environmental and social changes. The proposed rule would further emphasize the role of science in the planning process and the importance of evaluating the resource, environmental, ecological, social, and economic conditions at the onset of planning. The proposed rule would affirm the important role of other Federal agencies, State and local governments, Indian tribes, and the public during the planning process, and would enhance opportunities for public involvement and transparency during the preparation of resource management plans. Finally, the proposed rule would make revisions to clarify existing text and use plain language to improve the readability of the planning regulations. This notice extends the public comment period for 30 days beyond the initial comment-period deadline.

**DATES:** Send your comments on this proposed rule to the BLM on or before May 25, 2016. The BLM need not consider, or include in the administrative record for the final rule, comments that the BLM receives after the close of the comment period or comments delivered to an address other than those listed below (see **ADDRESSES**).

**ADDRESSES:** *Mail:* U.S. Department of the Interior, Director (630), Bureau of Land Management, Mail Stop 2134 LM, 1849 C St. NW., Washington, DC 20240, Attention: 1004-AE39. *Personal or messenger delivery:* Bureau of Land Management, 20 M Street SE., Room 2134 LM, Attention: Regulatory Affairs, Washington, DC 20003. *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions at this Web site.

**FOR FURTHER INFORMATION CONTACT:** Leah Baker, Division Chief, Decision Support, Planning and NEPA, at 202-912-7282, for information relating to the BLM's national planning program or the substance of this proposed rule. For information on procedural matters or the rulemaking process, you may contact Charles Yudson at 202-912-7437. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 to contact the above individuals during normal business hours. FIRS is available 24 hours a day, 7 days a week to leave a message or question with the above individuals. You will receive a reply during normal business hours.