

Dated: October 7, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-26055 Filed 10-13-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0128]

#### Prescription Drug User Fee Act; Reopening of Comment Period

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

**ACTION:** Notice; reopening of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening until April 29, 2016, the comment period for the notice of public meeting that appeared in the **Federal Register** of May 13, 2015 (80 FR 27323). In the notice of public meeting, FDA invited public comment as the Agency begins the process to reauthorize the Prescription Drug User Fee Act (PDUFA) in fiscal years (FYs) 2018 to 2022. The Agency is taking this action to allow interested persons additional time to submit comments.

**DATES:** FDA is reopening the comment period on the notice of public meeting published May 13, 2015 (80 FR 27323). Submit either electronic or written comments by April 29, 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-2010-N-0128 for "Prescription Drug User Fee Act; Reopening of Comment Period." 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>.

*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:** Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993-0002, 301-796-5003.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 13, 2015, FDA published a notice of public meeting with a 30-day comment period following the public meeting and invited comments as the Agency began the process to reauthorize PDUFA in FYs 2018 to 2022.

FDA is reopening the comment period until April 29, 2016. The Agency believes that reopening the comment period for the notice of public meeting will allow adequate time for interested persons to submit comments.

Dated: October 7, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-D-3399]

#### Recommendations for Microbial Vectors Used for Gene Therapy; Draft Guidance for Industry; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled "Recommendations for Microbial Vectors Used for Gene Therapy; Draft Guidance for Industry." The draft guidance provides investigational new drug application (IND) sponsors, with recommendations concerning IND submissions for microbial vectors used for gene therapy (MVGTS) in early-phase clinical trials. MVGTs meet the regulatory definition of

“biological product”, when such products are applicable to the prevention, treatment, or cure of a disease or condition of human beings. The draft guidance focuses on the chemistry, manufacturing, and control (CMC) information that sponsors should submit in an IND for MVGTs and provides an overview of preclinical and clinical considerations for these products. The draft guidance, when finalized, will supplement the guidance entitled, “Guidance for FDA Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs),” dated April 2008 (April 2008 Guidance).

**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 December 14, 2015.

**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-2015-D-3399 for “Recommendations for Microbial Vectors Used for Gene Therapy; Draft Guidance for Industry.” 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.

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. 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 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Paul E. Levine, Jr., 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**

FDA is announcing the availability of a draft document entitled, “Recommendations for Microbial Vectors Used for Gene Therapy; Draft Guidance for Industry.” The draft guidance provides IND sponsors, with recommendations concerning IND submissions for MVGTs in early-phase clinical trials. MVGTs meet the definition of “biological product” in section 351(i) of the Public Health Service Act (42 U.S.C. 262), when such products are applicable to the prevention, treatment, or cure of a disease or condition of human beings. MVGTs include bacterial vectors such as *Salmonella*, *Listeria*, or *E. coli* genetically modified to express human tumor antigens, cytokines, growth factors, enzymes, therapeutic proteins, or nucleotides. MVGTs may also be generated by the modification (deletion, truncation, or point mutation) of chromosomal or episomal genes and by the insertion of foreign genetic material into the chromosome, or into naturally occurring episomes; or by the introduction of one or more plasmids. The MVGTs may consist of microbes that are either live, replication restricted (division under specific growth conditions), capable of limited or no cell divisions, or killed, or a combination of these forms. The guidance focuses on the CMC information that sponsors should submit in an IND for MVGTs and provides an overview of preclinical and clinical considerations for these products.

In the **Federal Register** of April 10, 2008 (73 FR 19511), FDA announced the availability of the April 2008 Guidance. In that guidance, FDA provided sponsors of a human gene therapy IND, including those with combination products that contain a human gene therapy biological product with a drug or device as part of the final product, with recommendations on CMC information that is to be included in an original IND. That guidance also provided instruction to FDA CMC reviewers about the information to record and assess as part of an IND review. The draft guidance, when finalized, will supplement the April 2008 Guidance.

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 recommendations for MVGTs. It does not establish 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 parts 211, 610, and 312 have been approved under OMB control numbers 0910–0139 and 0910–0114, respectively.

## III. 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.regulations.gov>.

Dated: October 7, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Service Administration

#### Advisory Committee on Training in Primary Care Medicine and Dentistry; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

*Name:* Council on Graduate Medical Education (COGME).

*Dates and Times:* October 29, 2015 (10:30 a.m.–4:30 p.m.).

*Place:* Conference Call/Webinar Format.

*Status:* The meeting will be open to the public.

*Purpose:* The COGME provides advice and recommendations to the Secretary of the Department of Health and Human Services (the Secretary) on a range of issues including the supply and distribution of physicians in the United States, current and future physician shortages or excesses, issues relating to foreign medical school graduates, the nature and financing of medical education training, and the development of performance measures and longitudinal evaluation of medical education programs. COGME's reports are submitted to the Secretary and ranking members of the Senate Committee on Health, Education, Labor, and Pensions and the House of Representatives Committee on Energy and Commerce.

HRSA will conduct an orientation for new members prior to the start of the meeting. COGME will start its official meeting at 10:30 a.m. After the orientation, discussion will focus on one of the recommendations from the March 2015 meeting, namely, to identify actions COGME can take within its current authorities to achieve the development of a National Strategic Plan for Graduate Medical Education.

*Agenda:* The COGME agenda will be available 2 days prior to the meeting on the HRSA Web site at <http://www.hrsa.gov/advisorycommittees/bhpradvisory/cogme/index.html>.

**SUPPLEMENTARY INFORMATION:** Requests to make oral comments or provide written comments to the COGME should be sent to Dr. Joan Weiss, Designated Federal Official, using the address and phone number below. Individuals who plan to participate on the conference call and webinar should notify Dr. Weiss at least 3 days prior to the meeting, using the address and phone number below. Members of the public

will have the opportunity to provide comments. Interested parties should refer to the meeting subject as the HRSA Council on Graduate Medical Education.

- The conference call-in number is 1–800–619–2521. The passcode is: 9271697.

- The webinar link is <https://hrsa.connectsolutions.com/cogme-2015/>.

*Contact:* Anyone requesting information regarding the COGME should contact Dr. Joan Weiss, Designated Federal Official within the Bureau of Health Workforce, Health Resources and Services Administration, in one of three ways: (1) Send a request to the following address: Dr. Joan Weiss, Designated Federal Official, Bureau of Health Workforce, Health Resources and Services Administration, Parklawn Building, Room 12C–05, 5600 Fishers Lane, Rockville, Maryland 20857; (2) call (301) 443–0430; or (3) send an email to [jweiss@hrsa.gov](mailto:jweiss@hrsa.gov).

**Jackie Painter,**

*Director, Division of the Executive Secretariat.*

[FR Doc. 2015–26053 Filed 10–13–15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

[Document Identifier: HHS–OS–0990–New–30D]

#### Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a new collection. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

**DATES:** Comments on the ICR must be received on or before November 13, 2015.

**ADDRESSES:** Submit your comments to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or via facsimile to (202) 395–5806.