

part 822 have been approved under OMB control number 0910-0449.

Dated: August 30, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-3233]

#### Request for Nominations for Voting Members on a Public Advisory Committee; Technical Electronic Product Radiation Safety Standards Committee

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting nominations for members to serve on the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) in the Center for Devices and Radiological Health. Nominations will be accepted for current and upcoming vacancies effective with this notice.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

**DATES:** Nominations received on or before November 5, 2018 will be given first consideration for membership on TEPRSSC. Nominations received after November 5, 2018 will be considered for nomination to the committee as later vacancies occur.

**ADDRESSES:** All nominations for membership should be sent electronically by accessing FDA's Advisory Committee Membership Nomination Portal at <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

**FOR FURTHER INFORMATION CONTACT:** Patricio G. Garcia, Office of Device

Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G610, Silver Spring, MD 20993-0002, 301-796-6875, email: [Patricio.Garcia@fda.hhs.gov](mailto:Patricio.Garcia@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is requesting nominations for voting members on TEPRSSC that include three general public representatives.

#### I. General Description of the Committee's Duties

The committee provides advice and consultation to the Commissioner of Food and Drugs (Commissioner) on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products, and may recommend electronic product radiation safety standards to the Commissioner for consideration.

#### II. Criteria for Voting Members

The committee consists of a core of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of science or engineering, applicable to electronic product radiation safety. Members will be invited to serve for overlapping terms of up to 4 years. Terms of more than 2 years are contingent upon the renewal of the committee by appropriate action prior to its expiration.

#### III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5

U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: August 31, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-19355 Filed 9-5-18; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-1999-D-0081, FDA-2008-D-0205, FDA-2018-D-2173, FDA-2018-D-2236, FDA-2018-D-2238, and FDA-2018-D-2258]

#### Draft Guidances Relating to the Development of Human Gene Therapy Products; Availability; Extension of Comment Period

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

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

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notices of availability for six draft guidance documents relating to the development of human gene therapy products that appeared in the **Federal Register** of July 12, 2018. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments and any new information.

**DATES:** FDA is extending the comment period on the six documents that published on July 12, 2018 (see **SUPPLEMENTARY INFORMATION**). Submit either electronic or written comments by December 10, 2018, to ensure that the Agency considers your comment on these draft guidances before it begins work on the final version of the guidances.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 10, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of December 10, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*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-1999-D-0081 for "Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up; Draft Guidance for Industry;" Docket No. FDA-2008-D-0205 for "Chemistry, Manufacturing, and Control Information for Human

Gene Therapy Investigational New Drug Applications; Draft Guidance for Industry;" Docket No. FDA-2018-D-2173 for "Long Term Follow-Up After Administration of Human Gene Therapy Products; Draft Guidance for Industry;" Docket No. FDA-2018-D-2236 for "Human Gene Therapy for Retinal Disorders; Draft Guidance for Industry;" Docket No. FDA-2018-D-2238 for "Human Gene Therapy for Hemophilia; Draft Guidance for Industry;" or Docket No. FDA-2018-D-2258 for "Human Gene Therapy for Rare Diseases; Draft Guidance for Industry." Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

**FOR FURTHER INFORMATION CONTACT:** Jenifer Stach, 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 July 12, 2018, FDA published notices of availability with a 90-day comment period for six draft guidance documents listed in the following table. Three of the six draft guidance documents provide recommendations to stakeholders developing gene therapies for retinal disorders, hemophilia, and rare diseases. The remaining three guidance documents provide recommendations to sponsors manufacturing gene therapies; namely, how to provide chemistry, manufacturing and controls information for gene therapy products, additional recommendations regarding the testing for replication competent retrovirus during the manufacture of retroviral vector-based gene therapy products and during the follow-up monitoring of patients who received retroviral vector-based gene therapy products, and recommendations regarding the design of long-term follow-up observational studies for the collection of data on delayed adverse events following administration of a gene therapy product. Comments were requested on these draft guidances by October 10, 2018.

SIX DRAFT GUIDANCES PUBLISHED JULY 12, 2018

Docket No.	Draft guidance document title	FR cite
FDA-1999-D-0081 .....	Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up; Draft Guidance for Industry.	83 FR 32309
FDA-2008-D-0205 .....	Chemistry, Manufacturing, and Control Information for Human Gene Therapy Investigational New Drug Applications; Draft Guidance for Industry.	83 FR 32307
FDA-2018-D-2173 .....	Long Term Follow-Up After Administration of Human Gene Therapy Products; Draft Guidance for Industry.	83 FR 32311
FDA-2018-D-2236 .....	Human Gene Therapy for Retinal Disorders; Draft Guidance for Industry .....	83 FR 32302
FDA-2018-D-2238 .....	Human Gene Therapy for Hemophilia; Draft Guidance for Industry .....	83 FR 32306

## SIX DRAFT GUIDANCES PUBLISHED JULY 12, 2018—Continued

Docket No.	Draft guidance document title	FR cite
FDA-2018-D-2258 .....	Human Gene Therapy for Rare Diseases; Draft Guidance for Industry .....	83 FR 32303

The Agency has received requests for a 60-day extension of the comment period for the six draft guidance documents. These requests conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the draft guidance documents.

FDA has considered these requests and is extending the comment period for the six draft guidance documents for 60 days, until December 10, 2018. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments.

## II. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>.

1. Letter from Robert Falb, Director, U.S. Policy and Advocacy, Alliance for Regenerative Medicine, to Dr. Peter Marks, Director, Center for Biologics Evaluation and Research, FDA (July 23, 2018).
2. Letter from Sesquile Ramon, Ph.D., Director, Science and Regulatory Affairs, Biotechnology Innovation Organization, to FDA Dockets Management Staff (August 3, 2018).

Dated: August 29, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-19303 Filed 9-5-18; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0147]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **FEDERAL REGISTER** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on “Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products.”

**DATES:** Submit either electronic or written comments on the collection of information by November 5, 2018.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 5, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of November 5, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### 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-2011-D-0147 for “Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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