those results, and (2) help assess how the PHHS Block Grant advances work of the public health system and provides evidence to support future budgetary requests.

The respondent universe consists of 61 PHHS Block Grant coordinators, or their designees, across 61 health departments (50 states, the District of Columbia, two tribes, five US territories, and three freely associated states). The assessment will be administered to PHHS Block Grant coordinators electronically via a web-based questionnaire. A link to the assessment will be provided by email invitation. The survey will be completed once every two years. The total annualized estimated burden is 46 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
PHHS Block Grant Coordinators, or Designees.	PHHS Block Grant Assessment	61	1	45/60	46
Total	.....	.....	.....	.....	46

Jeffrey M. Zirger,

Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018–19294 Filed 9–5–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3130]

Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions.'' This guidance document describes FDA's current approach to considering uncertainty in making benefit-risk determinations to support certain FDA premarket decisions for medical devices—premarket approval applications (PMAs), De Novo requests, and humanitarian device exemption (HDE) applications. This guidance document elaborates on the consideration of uncertainty as part of our overarching approach to a benefit-risk based framework that is intended to assure greater predictability, consistency, and efficiency through the application of least burdensome principles. This draft guidance also provides examples of how the principles for considering uncertainty could be applied in the context of clinical evidence and circumstances where greater uncertainty could be appropriate in premarket decisions, balanced by postmarket controls—PMAs for Breakthrough Devices and PMAs for devices for small patient populations. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by December 5, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2018–D–3130 for ''Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions; Draft 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Sonja Fulmer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5451, Silver Spring, MD 20993–0002, 240–402–5979.

SUPPLEMENTARY INFORMATION:

I. Background

The Medical Device Amendments of 1976 (Pub. L. 94–295) to the Federal Food, Drug, and Cosmetic Act (FD&C Act) established a risk-based framework for the regulation of medical devices. The law established a three-tiered risk classification system based on the risk posed to patients should the device fail to perform as intended. Under this system, devices that pose greater risks to patients are subject to more regulatory controls and requirements. Generally, in premarket decision-making for devices, there exists some uncertainty around benefits and risks. The Agency generally provides marketing authorization for a device when it meets the applicable standards, including that its benefits outweigh its risks.

In 2015, following pilots conducted over 4 years, FDA established the Expedited Access Pathway Program as a voluntary program for certain medical devices that address an unmet need in the treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Under this program, an eligible device subject to a PMA could be approved with greater uncertainty about the product's benefits and risks, provided that, among other requirements, the data still support a reasonable assurance of safety and effectiveness, including that the probable benefits of the device outweigh its risks for a patient population with unmet medical needs. For devices subject to PMA, the Agency has the authority to impose, when warranted, postmarket requirements, including post-approval studies and postmarket surveillance, as a condition of approval, which could be used to address this greater uncertainty.[1] In the Breakthrough Device provisions of the FD&C Act, as added by the 21st Century Cures Act (Cures Act) and amended by the FDA Reauthorization Act of 2017 (FDARA), Congress codified and expanded this program to include devices reviewed through a 510(k) notification.[2]

This draft guidance provides further information on how FDA considers uncertainty in benefit-risk determinations for PMAs, De Novo requests, and HDE applications.

[1] See sections 513(a)(3)(C), 515(c)(5)(C), 515(d)(1)(B)(ii), and 515B(e)(2)(C) of the FD&C Act (21 U.S.C. 360c(a)(3)(C), 360e(c)(5)(C), 360e(d)(1)(B)(ii), and 360e–3(e)(2)(C)); 21 CFR 814.82).

[2] See section 515B of the FD&C Act (21 U.S.C. 360e–3), as created by section 3051 of the Cures Act (Pub. L. 114–255) and amended by section 901 of FDARA (Pub. L. 115–52).

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on consideration of uncertainty in making benefit-risk determinations in medical device premarket approvals, De Novo classifications, and humanitarian device exemptions. 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.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions; Draft Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17039 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This 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 part 801 have been approved under OMB control number 0910–0485; the collections of information for De Novo classification requests have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; and the collections of information in 21 CFR

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

Dated: August 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19249 Filed 9–5–18; 8:45 am]

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.*

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]

BILLING CODE 4164–01–P

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.