announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–08446 Filed 4–25–19; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to the Board of Scientific Counselors, National Center for Injury Prevention and Control BSC, NCIPC

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) is seeking nominations for membership on the BSC, NCIPC. The BSC, NCIPC consists of 18 experts in fields associated with surveillance, basic epidemiologic research, intervention research, and implementation, dissemination, and evaluation of promising and evidence-based strategies for the prevention of injury and violence.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishments of the committee's objectives. Nominees will be selected based on expertise in the fields of pertinent disciplines involved in injury and violence prevention, including, but not limited to, epidemiology, statistics, trauma surgery, rehabilitation medicine, behavioral science/psychology, health economics, program evaluation, political science, law, criminology, informatics and other aspects of injury management. Federal employees will not be considered for membership. Members may be invited to serve for up to four-year terms.

Selection of members is based on candidates' qualifications to contribute to the accomplishment of BSC, NCIPC objectives *https://www.cdc.gov/injury/bsc/.*

DATES: Nominations for membership on the BSC, NCIPC must be received no later than May 31, 2019. Packages received after this time will not be considered for the current membership cycle.

ADDRESSES: All nominations should be emailed (recommended) to *ncipcbsc@CDC.GOV.*

FOR FURTHER INFORMATION CONTACT: Gwendolyn H. Cattledge, Ph.D., M.S.E.H., Designated Federal Officer and Deputy Associate Director for Science, NCIPC, CDC, 4770 Buford Highway NE, Mailstop F–63, Atlanta, GA 30341, Telephone (770) 488–1430, Email address: *ncipcbsc@cdc.gov.*

SUPPLEMENTARY INFORMATION: The U.S. Department of Health and Human Services policy stipulates that committee membership be balanced in terms of points of view represented, and the committee's function. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Committee members are Special Government Employees (SGEs), requiring the filing of financial disclosure reports at the beginning and annually during their terms. CDC reviews potential candidates for BSC, NCIPC membership each year, and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected candidates of their appointment near the start of the term in September or as soon as the HHS selection process is completed. Note that the need for different expertise varies from year to year and a candidate who is not selected in one year may be reconsidered in a subsequent year. SGE Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government. Candidates should submit the following items:

- Cover letter stating area of expertise
- Current curriculum vitae, including complete contact information (telephone numbers, mailing address, email address)
- At least one letter of recommendation from person(s) not employed by the U.S. Department of Health and Human Services. (Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by an HHS agency (*e.g.,* CDC, NIH, FDA, SAMHSA, etc.).

Nominations may be submitted by the candidate him- or herself, or by the person/organization recommending the candidate. The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–08442 Filed 4–25–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0363]

Characterization of Ultrahigh Molecular Weight Polyethylene Used in Orthopedic Devices; 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 a final guidance entitled ''Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices.'' The guidance identifies the types of UHMWPE commonly in use in orthopedic implants, as well as the recommended information and testing that should be included in premarket submissions for such devices.

DATES: The announcement of the guidance is published in the **Federal Register** on April 26, 2019.

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–2016–D–0363 for ''Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices.'' 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 guidance document entitled ''Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices'' to the Office of Policy, 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: Peter Allen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1512, Silver Spring, MD 20993–0002, 301–796–6402.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled ''Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices.'' FDA has developed this guidance document for members of industry who submit, and FDA staff who review, information regarding orthopedic devices using UHMWPE material. This guidance is intended to provide recommendations regarding the characterization and testing of orthopedic devices that use UHMWPE materials such as conventional UHMWPE, highly crosslinked UHMWPE, highly crosslinked UHMWPE containing antioxidants, and non-conventional UHMWPE. This guidance also outlines the information FDA recommends industry include in a regulatory submission to characterize the UHMWPE material (*e.g.,* material description, sterility, biocompatibility, mechanical properties, and chemical properties). FDA considered comments received on the draft guidance that appeared in the **Federal Register** of February 12, 2016 (81 FR 7543). FDA revised the guidance as appropriate in response to the comments.

II. Significance of 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 the characterization of UHMWPE used in orthopedic devices. 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 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 ''Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1300006 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. 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 the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
820	Quality System Regulation	0910–0073
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''	De Novo classification process	0910–0844
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756

Dated: April 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08465 Filed 4–25–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4206]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device User Fee Small Business Qualification and Certification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 28, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0508 and title ''Medical Device User Fee Small Business Qualification and Certification.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device User Fee Small Business Qualification and Certification

OMB Control Number 0910–0508—Extension

Medical device user fees were first established in 2002 by the Medical Device User Fee and Modernization Act (MDUFMA) (Pub. L. 107–250). User fees were renewed in 2007, with the Medical Device User Fee Amendments to the Food and Drug Administration Amendments Act of 2007 (MDUFA II), in 2012 with the Medical Device User Fee Amendments to the FDA Safety and Innovation Act (MDUFA III), and in 2017 with the Medical Device User Fee Amendments to the FDA Reauthorization Act of 2017 (MDUFA IV). MDUFA IV will be in place from October 1, 2017, until September 30, 2022.

A business that is qualified and certified as a ''small business'' is eligible for a substantial reduction in most of these user fees. The guidance document entitled ''Medical Device User Fee Small Business Qualification and Certification Guidance for Industry, Food and Drug Administration Staff and Foreign Governments'' describes the criteria FDA will use to decide whether an entity is eligible for a reduction in user fees and the process by which a business may request certification as a small business.

An applicant can qualify for a small business fee discount under MDUFMA if they reported gross receipts or sales of no more than $100 million on their Federal income tax return for the most recent tax year. If they have any affiliates, partners, or parent firms, the applicant must add the gross receipts or sales of the affiliates, partners, or parent firms to the applicant's, and the total must be no more than $100 million. If the applicant's gross receipts or sales are no more than $30 million, including all of their affiliates, partners, and parent firms, they will also qualify for a waiver of the fee for their first (ever) premarket application (product development protocol, biologics licensing application, or premarket report). An applicant must pay the full standard fee unless it provides evidence demonstrating to FDA that it meets the small business criteria (Form FDA 3602, ''MDUFA Small Business Certification Request for a Business Headquartered in the United States''). The evidence required by MDUFMA is a copy of the most recent Federal income tax return of the applicant, and any affiliate, partner, or parent firm. FDA will review these materials and decide whether an applicant is a small business within the meaning of MDUFMA.

MDUFA II provided an alternative way for a foreign business to qualify as a small business eligible to pay a significantly lower fee when a medical device user fee must be paid (Form FDA 3602A, ''MDUFA Foreign Small Business Certification Request for a Business Headquartered Outside the United States''). Before passage of MDUFA II, the only way a business could qualify as a small business was to submit a Federal (U.S.) income tax return showing its gross receipts or sales that did not exceed a statutory threshold, currently, $100 million. If a business could not provide a Federal income tax return, it did not qualify as a small business and had to pay the standard (full) fee. Because many foreign businesses have not, and cannot, file a Federal (U.S.) income tax return, this requirement effectively prevented those businesses from qualifying for the small business fee rates. Thus, foreign governments, including the European Union, objected. In lieu of a Federal income tax return, the MDUFA II allowed a foreign business to qualify as a small business by submitting a certification from its national taxing authority, the foreign equivalent of our Internal Revenue Service. This certification, referred to as a ''National Taxing Authority Certification,'' must: (1) Be in English; (2) be from the national taxing authority of the country in which the business is headquartered; (3) provide the business' gross receipts