TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity | FDA form No. | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|---|
| Initial consultation | None | 20 | 2 | 40 | 4 | 160 |
| Final consultation | 3665 | 12 | 1 | 12 | 150 | 1,800 |
| Total | | | | | | 1,960 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate is based on the information collection activities discussed below.

Initial Consultations

Initial consultations are generally a one-time burden, although a developer might return more than once to discuss additional issues before submitting a final consultation. As noted in the guidance, FDA encourages developers to consult early in the development phase of their products, and as often as necessary. Historically, firms developing a new bioengineered plant variety intended for food use have generally initiated consultation with FDA early in the process of developing such a variety, even though there is no legal obligation for such consultation. These consultations have served to make FDA aware of foods and food ingredients before these products are distributed commercially, and have provided FDA with the information necessary to address any potential questions regarding the safety, labeling, or regulatory status of the food or food ingredient. As such, these consultations have provided assistance to both industry and the Agency in exercising their mutual responsibilities under the FD&C Act.

FDA estimates that CVM and CFSAN jointly received an average of 40 initial consultations per year in the last 3 years via telephone, email, or written letter. Based on this information, we expect to receive no more than 40 annually in the next 3 years.

Final Consultations

Final consultations are a one-time burden. At some stage in the process of research and development, a developer will have accumulated the information that the developer believes is adequate to ensure that food derived from the new plant variety is safe and that it demonstrates compliance with the relevant provisions of the FD&C Act. The developer will then be in a position to conclude any ongoing consultation with FDA. The developer submits to FDA a summary of the safety and nutritional assessment that has been conducted about the bioengineered food that is intended to be introduced into commercial distribution. FDA evaluates the submission to ensure that all potential safety and regulatory questions have been addressed. FDA has developed a form that prompts a developer to include certain elements in the final consultation in a standard format: Form FDA 3665 entitled, ''Final Consultation for Food Derived From a New Plant Variety (Biotechnology Final Consultation).'' The form, and elements that would be prepared as attachments to the form, can be submitted in electronic format.

We base our estimate of the average time to prepare a submission on informal contact with firms that made one or more biotechnology consultation submission under the voluntary biotechnology consultation process. As such, we estimate the average time to prepare a submission for final consultation to be 150 hours.

Dated: March 21, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–06069 Filed 3–26–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–N–0965]**

### Request for Nominations for Voting Members on a Public Advisory Committee; Pharmacy Compounding Advisory 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 Pharmacy Compounding Advisory Committee (Committee), Division of Advisory Committee Consultant Management, Center for Drug Evaluation and Research. The Committee provides advice on scientific, technical, and medical issues concerning human drug compounding under the Federal Food, Drug, and Cosmetic Act (FD&C Act), and, as required, any other product for which FDA has regulatory responsibility, and makes appropriate recommendations to the Commissioner of Food and Drugs.

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 May 29, 2018, will be given first consideration for membership on the Pharmacy Compounding Advisory Committee. Nominations received after May 29, 2018, will be considered for nominations to the Committee as later vacancies occur.

**ADDRESSES:** All nominations for membership should be sent electronically by logging into the FDA Advisory Nomination Portal: *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.

**FOR FURTHER INFORMATION CONTACT:** *Regarding all nomination questions for membership, the primary contact is:* Cindy Chee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002; 301–796–9001, Fax: 301–847–8533, email: *PCAC@fda.hhs.gov.*

Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website by using the following link: *https://www.fda.gov/AdvisoryCommittees/default.htm.*

**SUPPLEMENTARY INFORMATION:** FDA is requesting nominations for voting members on the Pharmacy Compounding Advisory Committee.

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

The Committee provides advice on scientific, technical, and medical issues concerning human drug compounding under sections 503A and 503B of the FD&C Act (21 U.S.C. 353a and 353b), and, as required, any other product for which FDA has regulatory responsibility, and makes appropriate recommendations to the Commissioner of Food and Drugs.

In implementing sections 503A and section 503B of the FD&C Act, the Agency may consult the Committee on: (1) Drug products for inclusion on a list of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective, and therefore cannot be compounded; (2) bulk drug substances for inclusion on lists of bulk drug substances that may be used in compounding; and (3) drug products for inclusion on a list of drug products that present demonstrable difficulties for compounding.

Meetings are held approximately two to three times a year, announced in the **Federal Register**, and are open to the public except as determined otherwise by the Commissioner or designee in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act. Notice of all meetings shall be given to the public.

**II. Criteria for Voting Members**

The Committee consists of a core of 12 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine, and related specialties. These members will include representatives from the National Association of Boards of Pharmacy, the U.S. Pharmacopeia, pharmacists with current experience and expertise in compounding, physicians with background and knowledge in compounding, and patient and public health advocacy organizations. Almost all non-Federal members of this committee serve as Special Government Employees. Members will be invited to serve for terms of up to 4 years.

**III. Nomination Procedures**

Any interested person may nominate one or more qualified individuals for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee 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: March 21, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–06062 Filed 3–26–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–N–0235]**

### Orthopaedic Sensing, Measuring, and Advanced Reporting Technology Devices; Public Workshop; Request for Comments; Amendment of Notice

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing an amendment to the notice of public workshop entitled ''Orthopaedic Sensing, Measuring, and Advanced Reporting Technology (SMART) Devices.'' That workshop was announced in the **Federal Register** of February 13, 2018. The amendment is being made to reflect a change in the **DATES** portion of the document. There are no other changes.

**FOR FURTHER INFORMATION CONTACT:** Andrew Baumann, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 2110, Silver Spring, MD 20993, 301–796–2508, *andrew.baumann@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of February 13, 2018 (83 FR 6188), FDA announced that a public workshop entitled ''Orthopaedic Sensing, Measuring, and Advanced Reporting Technology (SMART) Devices'' would be held on April 30, 2018. On page 6188, in the third column, the **DATES** portion of the document is changed to reflect new start and end times to read as follows:

**DATES:** The public workshop will be held on April 30, 2018, from 8 a.m. to 5:30 p.m. Submit either electronic or written comments on this public workshop by May 29, 2018. See the **SUPLLEMENTARY INFORMATION** section for registration date and information.

Dated: March 21, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–06064 Filed 3–26–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–D–0943]**

### Elemental Impurities in Animal Drug Products—Questions and Answers; Draft Guidance for Industry; 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 draft guidance for industry (GFI) #255 entitled ''Elemental Impurities in Animal Drug Products—Questions and Answers.'' This guidance is intended to assist sponsors of animal drug products in addressing changes in the United States Pharmacopeia (USP) requirements for the control of elemental impurities in drug products marketed in the United States.

**DATES:** Submit either electronic or written comments on the draft guidance by May 29, 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