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Act, the Agency may consult the Committee on: (1) Drug products for inclusion on a list of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective, and therefore cannot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

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–0943 for ''Elemental Impurities in Animal Drug Products—Questions and Answers.'' 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)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Michael Brent, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0647, email: *michael.brent@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft GFI #255 entitled ''Elemental Impurities in Animal Drug Products—Questions and Answers.'' This document provides recommendations to sponsors regarding the control of elemental impurities in animal drug products, including all dosage forms and routes of administration.

II. Significance of Guidance

This level 1 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 ''Elemental Impurities in Animal Drug Products—Questions and Answers.'' 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. 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 section 512(n)(1) of the FD&C Act (21 U.S.C. 360b(n)(1)) have been approved under OMB control number 0910–0669. The collections of information in 21 CFR 514.1 and 514.8 have been approved under OMB control number 0910–0032.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *https://www.regulations.gov.*

Dated: March 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–06061 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–2016–N–0001]

Advisory Committee; Gastrointestinal Drugs Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Gastrointestinal Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Gastrointestinal Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until March 3, 2020.

DATES: Authority for the Gastrointestinal Drugs Advisory Committee will expire on March 3, 2020, unless the Commissioner formally determines that renewal is in the public interest.