

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the Agency may consult the Committee on: (1) Drug products for inclusion on a list of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective, and therefore cannot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

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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 **SUPPLEMENTARY INFORMATION** section for registration date and information.

Dated: March 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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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