

Dated: March 16, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: April 5, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-4561]

Advisory Committee; Bone, Reproductive and Urologic 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 Bone, Reproductive and Urologic 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 Bone, Reproductive and Urologic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until March 23, 2020.

DATES: Authority for the Bone, Reproductive and Urologic Drugs Advisory Committee will expire on March 23, 2020, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Kalyani Bhatt, Division of Advisory Committee and Consultant Management, 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, email: BRUDAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Bone, Reproductive and Urologic Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Committee advises the Commissioner or designee in

discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drug products for use in the practice of osteoporosis and metabolic bone disease, obstetrics, gynecology, urology, and related specialties, and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of osteoporosis and metabolic bone disease, obstetrics, gynecology, urology, pediatrics, epidemiology, or statistics and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/ucm107572.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: April 5, 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-0981]

Preparation for International Cooperation on Cosmetics Regulation Twelfth Annual Meeting; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the following public meeting entitled “International Cooperation on Cosmetics Regulation (ICCR)—Preparation for ICCR-12 Meeting.” The purpose of the public meeting is to invite public input on various topics pertaining to the regulation of cosmetics. We may use this input to help us prepare for the ICCR-12 meeting that will be held July 10 to 12, 2018, in Tokyo, Japan.

DATES: The public meeting will be held on June 7, 2018, from 2 p.m. to 4 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr., Wiley Auditorium (first floor), College Park, MD 20740.

FOR FURTHER INFORMATION CONTACT: Jonathan Hicks, Office of Cosmetics and Colors, Food and Drug Administration, 5001 Campus Dr. (HFS-125), College Park, MD 20740, jonathan.hicks@fda.hhs.gov, 240-402-1375.

SUPPLEMENTARY INFORMATION:

I. Background

The intention of the ICCR multilateral framework is to pave the way for the removal of regulatory obstacles to international trade while maintaining global consumer protection. The purpose of the meeting is to invite public input on various topics pertaining to the regulation of cosmetics. We may use this input to help us prepare for the ICCR-12 meeting that will be held July 10 to 12, 2018, in Tokyo, Japan.

ICCR is a voluntary international group of cosmetics regulatory authorities from Brazil, Canada, the European Union, Japan, and the United States of America. These regulatory authority members will engage in constructive dialogue with their relevant cosmetics industry trade