Pathway; Guidance for Industry and Food and Drug Administration Staff'' (document number 19008), ''Orthopedic Non-Spinal Metallic Bone Screws and Washers—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff'' (document number 19009), or ''Magnetic Resonance (MR) Receive-only Coil—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff'' (document number 19011) may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While these guidances contain no collection of information, they do refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for these guidances. The previously approved collections of information are subject to review by OMB under the PRA. 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 or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756

Dated: December 7, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–27248 Filed 12–10–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA- 2019–N–4203]

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 the March 23, 2022, expiration date.

DATES: Authority for the Bone, Reproductive and Urologic Drugs Advisory Committee will expire on March 23, 2022 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 is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Bone, Reproductive and Urologic Drugs Advisory 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.

Under its Charter, 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 representative member who is identified with industry interests. There may also be an alternate industry representative.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/human-drug-advisory-committees/bone-reproductive-and-urologic-drugs-advisory-committee-formerly-reproductive-health-drugs-advisory* 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: December 8, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–27289 Filed 12–10–20; 8:45 am]

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