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.

[FR Doc. 2018–07410 Filed 4–10–18; 8:45 am]

BILLING CODE 4120–01–P

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.

[FR Doc. 2018–07437 Filed 4–10–18; 8:45 am]

BILLING CODE 4164–01–P

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

associations and public advocacy groups. Currently, the ICCR members are: The Brazilian Health Surveillance Agency; Health Canada; the European Commission Directorate-General for Internal Market, Industry, Entrepreneurship, and Small and Medium-sized Enterprises; the Ministry of Health, Labor, and Welfare of Japan; and FDA. All decisions are made by consensus and will be compatible with the laws, policies, rules, regulations, and directives of the respective administrations and governments. Members will implement and/or promote actions or documents within their own jurisdictions and seek convergence of regulatory policies and practices. Successful implementation will need input from stakeholders.

II. Topics for Discussion at the Public Meeting

We will make the agenda for the public meeting available on the internet at *https://www.fda.gov/Cosmetics/InternationalActivities/ICCR/default.htm.* Depending on the number of requests for oral presentations, we intend to have an agenda available by May 31, 2018.

III. Participating in the Public Meeting

Registration: To register for the public meeting, send registration information (including your name, title, affiliation, address, email, and telephone), to Jonathan Hicks by May 24, 2018 (see **FOR FURTHER INFORMATION CONTACT**). If you would like to listen to the meeting by phone, please submit a request for a dial-in number by May 24, 2018. If you need special accommodations due to a disability, please contact Jonathan Hicks by May 31, 2018.

Requests for Oral Presentations: If you wish to make an oral presentation, you should notify Jonathan Hicks by May 24, 2018, and submit a brief statement of the general nature of the evidence or arguments that you wish to present, your name, title, affiliation, address, email, and telephone, and indicate the approximate amount of time you need to make your presentation. You may present proposals for future ICCR agenda items, data, information, or views, in person or in writing, on issues pending at the public meeting. There will be no presentations by phone. Time allotted for oral presentations may be limited to 10 minutes or less for each presenter, depending on the number of requests received.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may also be viewed at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20850.

Dated: April 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07416 Filed 4–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1336]

Oxford Pharmaceuticals, LLC, et al.; Withdrawal of Approval of 18 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 18 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of May 11, 2018.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945, *Trang.Tran@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040252	Carisoprodol and Aspirin Tablets USP, 200 milligrams (mg)/325 mg.	Oxford Pharmaceuticals, LLC, 301 Leaf Lake Pkwy., Birmingham, AL 35211.
ANDA 040283	Carisoprodol, Aspirin, and Codeine Phosphate Tablets USP, 200 mg/325 mg/16 mg.	Do.
ANDA 061214	Tetracycline Hydrochloride (HCl) Capsules USP, 250 mg and 500 mg.	Roxane Laboratories, Inc., 1809 Wilson Rd., Columbus, OH 43228.
ANDA 061682	Tetracycline HCl Tablets, 500 mg	Mylan Pharmaceuticals Inc., P.O. Box 4293, Morgantown, WV 26505.
ANDA 062212	Totacillin (ampicillin/ampicillin trihydrate) Capsules, Equivalent to (EQ) 250 mg base and EQ 500 mg base.	GlaxoSmithKline, Five Moore Dr., P.O. Box 13398, Research Triangle Park, NC 27709.
ANDA 062654	Rocephin (ceftriaxone sodium) for Injection, EQ 500 mg base/vial, EQ 1 gram (g) base/vial, and EQ 2 g base/vial.	Hoffman La-Roche, Inc., c/o Genentech, Inc., 1 DNA Way, MS 241B, South San Francisco, CA 94080.
ANDA 062680	Oxacillin Sodium for Injection (Pharmacy Bulk Package)	ACS Dobfar S.p.A., c/o Interchem Corp., 120 Route 17 North, Paramus, NJ 07653.
ANDA 065124	Cefotaxime for Injection USP, EQ 500 mg base/vial, EQ 1 g base/vial, and EQ 2 g base/vial.	Lupin Ltd., c/o Lupin Pharmaceuticals, Inc., 111 South Calvert St., Harborplace Tower, 24th Floor, Baltimore, MD 21202.
ANDA 065263	Ceftriaxone for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package).	Do.
ANDA 074845	Diltiazem HCl Extended-Release Capsules USP, 60 mg, 90 mg, and 120 mg.	Biovail Corp. International, Subsidiary of Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.