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.

Application No.	Drug	Applicant
ANDA 077173	Ondansetron Injection USP, EQ 2 mg base/milliliter (mL)	Sun Pharmaceutical Industries Ltd., c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540.
ANDA 078598	Ciprofloxacin Ophthalmic Solution USP, EQ 0.3% base	Amring Pharmaceuticals, Inc., 1235 Westlakes Dr., Suite 205, Berwyn, PA 19312.
ANDA 078805	Irinotecan HCl Injection, 20 mg/mL	Sun Pharma Global FZE, c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540.
ANDA 086024	Capital and Codeine (acetaminophen and codeine phosphate) Oral Suspension USP, 120 mg/12 mg per 5 mL.	Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 091180	Dorzolamide HCl and Timolol Maleate Ophthalmic Solution, EQ 2% base/EQ 0.5% base.	Zambon S.p.A., c/o Camargo Pharmaceutical Services, LLC, 9825 Kenwood Rd., Suite 203, Cincinnati, OH 45242.
ANDA 203176	Nevirapine Tablets USP, 200 mg	Technology Organized, LLC, 9191 Point Replete Dr., Fort Belvoir, VA 22060.
ANDA 204900	Amlodipine Besylate Tablets USP, EQ 2.5 mg base, EQ 5 mg base, and EQ 10 mg base.	Sovereign Pharmaceuticals, LLC, 7590 Sand St., Fort Worth, TX 76118.
ANDA 209480	Clozapine Tablets USP, 25 mg, 50 mg, 100 mg, and 200 mg.	Zydus Pharmaceuticals USA, Inc., 73 Route 31 North, Pennington, NJ 08534.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of May 11, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on May 11, 2018 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: April 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07440 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–1095]

Request for Nominations for Individuals and Consumer Organizations for Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing. FDA is also requesting nominations for voting and/or nonvoting consumer representatives to serve on advisory committees and/or panels for which vacancies currently exist or are expected to occur in the near future. Nominees recommended to serve as a voting or nonvoting consumer representative may be self-nominated or may be nominated by a consumer organization.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees, and therefore encourages nominations of appropriately qualified candidates from these groups.

DATES: Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests on an FDA advisory committee or panel may send a letter or email stating that interest to FDA (see **ADDRESSES**) by May 11, 2018, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see **ADDRESSES**) by May 11, 2018. Nominations will be accepted for current vacancies and for those that will or may occur through July 31, 2018.

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process and consumer representative nominations should be submitted electronically to *ACOMSSubmissions@fda.hhs.gov,* by mail or delivery service to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002, or by Fax: 301–847–8640.

Consumer representative nominations should be submitted electronically by logging into the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm;* by mail or delivery service to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002; or by Fax: 301–847–8640. Additional information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: For questions relating to participation in the selection process: Kimberly Hamilton, Advisory Committee Oversight and Management Staff (ACOMS), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002, 301–796–8220, email: *kimberly.hamilton@fda.hhs.gov.*

For questions relating to specific advisory committees or panels, contact the appropriate contact person listed in table 1.