person on or before November 1, 2018. Oral presentations from the public will be scheduled between approximately 12:45 p.m. to 1:45 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 24, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 25, 2018.

Closed Committee Deliberations: On November 8, 2018, from 1:50 p.m. to 2:45 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The recommendations of the advisory committee regarding the progress of the investigator's research will, along with other information, be used in making personnel and staffing decisions regarding individual scientists.

We believe that public discussion of these recommendations on individual scientists would constitute an unwarranted invasion of personal privacy.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Serina Hunter-Thomas at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21137 Filed 9–27–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3569]

GlaxoSmithKline, LLC, et al.; Withdrawal of Approval of 24 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 24 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants 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 October 29, 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 applicants 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 described 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 061336	Bactocill (oxacillin sodium) Capsules, Equivalent to (EQ) 250 milligrams (mg) base and EQ 500 mg base.	GlaxoSmithKline, LLC, Five Moore Dr., P.O. Box 13398, Research Triangle Park, NC 27709.
ANDA 061773	Kefzol (cefazolin) for Injection USP, EQ 250 mg base/vial, EQ 500 mg base/vial, EQ 1 gram (g) base/vial, EQ 10 g base/vial, and EQ 20 g base/vial.	ACS Dobfar S.p.A., c/o Interchem Corp., 120 Rte. 17 North, Paramus, NJ 07652.
ANDA 062615	Nystatin Vaginal Inserts USP, 100,000 units	Odyssey Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 063304	Clindamycin Phosphate Topical Solution USP, EQ 1% base	Wockhardt Bio AG, c/o Morton Grove Pharmaceuticals, Inc., 6451 Main St., Morton Grove, IL 60053.
ANDA 065001	Cefuroxime for Injection USP, EQ 750mg base/vial and EQ 1.5 g base/vial.	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 065002	Cefuroxime for Injection USP, EQ 7.5 g base/vial (Pharmacy Bulk Package).	Do.
ANDA 070736	Ibuprofen Tablets USP, 300 mg, 400 mg, and 600 mg	Aurolife Pharma, LLC, 279 Princeton Hightstown Rd., East Windsor, NJ 08520.
ANDA 071202	Sensorcaine—MPF Spinal (bupivacaine hydrochloride (HCl)) in Dextrose Injection 8.25% USP, 0.75%.	Fresenius Kabi USA, LLC.
ANDA 071846	Nitroglycerin in Dextrose 5% Injection, 10 mg/100 milliliter (mL).	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045.
ANDA 071847	Nitroglycerin in Dextrose 5% Injection, 20 mg/100 mL	Do.
ANDA 071848	Nitroglycerin in Dextrose 5% Injection, 40 mg/100 mL	Do.
ANDA 072629	Albuterol Tablets USP, EQ 2 mg base	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 074991	Loperamide HCl Oral Solution, 1 mg/5 mL	Duramed Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.

Application No.	Drug	Applicant
ANDA 077312	Fentanyl Citrate Troche/Lozenge, EQ 0.2 mg base, EQ 0.4 mg base, EQ 0.6 mg base, EQ 0.8 mg base, EQ 1.2 mg, and EQ 1.6 mg base.	Par Pharmaceutical, Inc., One Ram Ridge Rd., Chestnut Ridge, NY 10977.
ANDA 077853	Metformin HCl Tablets USP, 500 mg, 850 mg, and 1 g	Provident Pharmaceutical, Inc., c/o Vintage Pharmaceuticals, LLC, 1400 Atwater Dr., Malvern, PA 19355.
ANDA 080355	Hydrocortisone Tablets USP, 20 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., Morris Corporate Center III, 400 Interpace Pkwy., Parsippany, NJ 07054.
ANDA 080377	Lidocaine HCl with Epinephrine Injection, 1%; 0.01 mg/mL and 2%; 0.01 mg/mL.	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 087100	Chlorthalidone Tablets USP, 25 mg	Do.
ANDA 087211	Methocarbamol and Aspirin Tablets, 400 mg/325 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 090184	Podofilox Topical Solution, 0.5%	Bausch & Lomb, Inc., Subsidiary of Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 202002	Imiquimod Cream, 5%	Strides Pharma Global Pte Ltd., c/o Strides Pharma, Inc., 2 Tower Center Blvd., Suite 1102, East Brunswick, NJ 08816.
ANDA 203247	Sodium Fluoride F–18 Injection, 10–200 millicurie (mCi)/mL ..	University of Texas MD Anderson Cancer Center, Cyclotron Radiochemistry Facility, 1881 East Rd., Unit 1903, Houston, TX 77054.
ANDA 203933	Ammonia N–13 Injection, 3.75–37.5 mCi/mL	Do.
ANDA 205072	Cefadroxil Capsules USP, EQ 500 mg base	CSPC Ouyi Pharmaceutical Co., Ltd., c/o Megalith Pharmaceuticals, Inc., 9625 Hillside Rd., Rancho Cucamonga, CA 91737.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of October 29, 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 October 29, 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: September 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21199 Filed 9–27–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3522]

Use of the Names of Dairy Foods in the Labeling of Plant-Based Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) invites comments on the labeling of plant-based products with names that include the names of dairy foods such as ''milk,'' ''cultured milk,'' ''yogurt,'' and ''cheese.'' We are interested in learning how consumers use these plant-based products and how they understand terms such as, for example, ''milk'' or ''yogurt'' when included in the names of plant-based products. We also are interested in learning whether consumers are aware of and understand differences between the basic nature, characteristics, ingredients, and nutritional content of plant-based products and their dairy counterparts. We are taking this action to inform our development of an approach to the labeling of plant-based products that consumers may substitute for dairy foods.

DATES: Submit either electronic or written comments on this document by November 27, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 27, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 27, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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 comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.