and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lauren D. Tesh, 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, Fax: 301–847–8533, email: *AMDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will discuss new drug application (NDA) 210693, ciprofloxacin dispersion for inhalation, sponsored by Aradigm Corp., for the proposed indication of treatment of non-cystic fibrosis bronchiectasis patients with chronic lung infections with *Pseudomonas aeruginosa.*

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before December 27, 2017, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 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 December 18, 2017. 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 December 19, 2017.

Persons attending FDAs 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 special accommodations due to a disability, please contact Lauren D. Tesh at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site 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: November 24, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–25911 Filed 11–30–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6591]

Barr Laboratories, Inc. et al.; Withdrawal of Approval of 68 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 68 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 January 2, 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.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in table 1 in this document 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.

TABLE 1

Application No.	Drug	Applicant
ANDA 040135	Estropipate Tablets USP, 0.75 milligrams (mg), 1.5 mg, and 3 mg.	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 040755	Carisoprodol Tablets USP, 350 mg	Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc., 270 Prospect Plains Rd., Cranbury, NJ 08512.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 062588	Gentamicin Sulfate in 0.9% Sodium Chloride Injection, Equivalent to (EQ) 1.2 mg base/milliliter (mL), EQ 1.4 mg base/mL, EQ 1.6 mg base/mL, EQ 1.8 mg base/mL, EQ 2 mg base/mL, EQ 60 mg base/100 mL, EQ 70 mg base/100 mL, EQ 80 mg base/100 mL, EQ 90 mg base/100 mL, and EQ 100 mg base/100 mL.	Hospira, Inc., a Pfizer Company, 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045.
ANDA 062591	Kefurox (cefuroxime) for Injection USP, EQ 750 mg base/vial, EQ 1.5 grams (g) base/vial, and EQ 7.5 g base/vial.	ACS Dobfar S.p.A., c/o Interchem Corp., 120 Route 17 North, Paramus, NJ 07652.
ANDA 062756	Primaxin IV (imipenem and cilastatin) for Injection USP, 250 mg/vial; EQ 250 mg base/vial and 500 mg/vial; EQ 500 mg base/vial.	Merck Sharp & Dohme Corp., Subsidiary of Merck & Co., Inc., 1 Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889.
ANDA 063207	Cefazolin for Injection USP, EQ 1 g base/vial	Facta Farmaceutici S.p.A., c/o Interchem Corp., 120 Route 17 North, Suite 115, Paramus, NJ 07652.
ANDA 063209	Cefazolin for Injection USP, EQ 10 g base/vial and EQ 20 g base/vial (Pharmacy Bulk Package).	Do.
ANDA 063214	Cefazolin for Injection USP, EQ 500 mg base/vial	Do.
ANDA 063263	Amikacin Sulfate Injection USP, EQ 50 mg base/mL	Hospira, Inc.
ANDA 065268	Ceftriaxone for Injection USP, EQ 1 g base/vial and EQ 2 g base/vial.	Facta Farmaceutici S.p.A.
ANDA 065269	Ceftriaxone for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package).	Do.
ANDA 065348	Cefotaxime for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package).	Cephazone Pharma, LLC, 250 E. Bonita Ave., Pomona, CA 91767.
ANDA 065464	Cefoxitin for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package).	ACS Dobfar S.p.A.
ANDA 065467	Cefoxitin for Injection USP, EQ 1 g base/vial and EQ 2 g base/vial.	Do.
ANDA 070048	Cotrim D.S. (sulfamethoxazole and trimethoprim) Tablets USP, 800 mg/160 mg.	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 070195	Valproic Acid Capsules USP, 250 mg	Catalent Pharma Solutions, LLC, 2725 Scherer Dr. North, St. Petersburg, FL 33716.
ANDA 070513	Tolazamide Tablets USP, 100 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 070514	Tolazamide Tablets USP, 250 mg	Do.
ANDA 071358	Tolazamide Tablets USP, 250 mg	Sun Pharmaceutical Industries, Inc., 270 Prospect Plains Rd., Cranbury, NJ 08512.
ANDA 071359	Tolazamide Tablets USP, 500 mg	Do.
ANDA 071667	Ibuprofen Tablets USP, 600 mg	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 071668	Ibuprofen Tablets USP, 800 mg	Do.
ANDA 071735	Ibuprofen Tablets USP, 200 mg	Contract Pharmacal Corp., c/o SciRegs International Inc., 6333 Summercrest Dr., Columbia, MD 21045.
ANDA 071773	Ibuprofen Tablets USP, 200 mg	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 073254	Loperamide Hydrochloride (HCl) Tablets USP, 2 mg	Contract Pharmacal Corp.
ANDA 074075	Clemastine Fumarate Syrup, EQ 0.5 mg base/5 mL	Actavis Mid Atlantic, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 074536	Haloperidol Oral Solution USP, EQ 1 mg base/mL	Do.
ANDA 074782	Ibuprofen Capsules, 200 mg	Contract Pharmacal Corp.
ANDA 074789	Naproxen Sodium Tablets USP, EQ 200 mg base	Do.
ANDA 074931	Ibuprofen Tablets USP, 200 mg	Do.
ANDA 074961	Cimetidine Tablets USP, 200 mg	Do.
ANDA 074963	Cimetidine Tablets USP, 200 mg	Do.
ANDA 075094	Ranitidine Tablets USP, EQ 75 mg base	Do.
ANDA 075588	Ibuprofen and Pseudoephedrine HCl Tablets USP, 200 mg/30 mg.	Do.
ANDA 077058	Pantoprazole Sodium Delayed-Release Tablets USP, EQ 20 mg base and EQ 40 mg base.	Sun Pharmaceutical Industries, Ltd.
ANDA 077172	Ondansetron Injection USP, EQ 2 mg base/mL	Do.
ANDA 077329	Octreotide Acetate Injection, EQ 0.05 mg base/mL, EQ 0.1 mg base/mL, and EQ 0.5 mg base/mL.	Do.
ANDA 077330	Octreotide Acetate Injection, EQ 0.2 mg base/mL	Do.
ANDA 077331	Octreotide Acetate Injection, EQ 1 mg base/mL	Do.
ANDA 078108	Sertraline HCl Tablets, EQ 25 mg base, EQ 50 mg base, and EQ 100 mg base.	Do.
ANDA 078478	Torsemide Tablets, 5 mg, 10 mg, 20 mg, and 100 mg	Do.
ANDA 083000	Folic Acid Tablets, 1 mg	Ivax Pharmaceutical USA, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 085549	Reserpine, Hydralazine HCl, and Hydrochlorothiazide Tablets, 0.1 mg/25 mg/15 mg.	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 086109	Tolbutamide Tablets USP, 500 mg	Do.
ANDA 086577	Trimethobenzamide HCl Injection, 100 mg/mL	Do.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 087191	Triamcinolone Acetonide Lotion USP, 0.025%	Alpharma U.S. Pharms, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 087398	Spironolactone and Hydrochlorothiazide Tablets USP, 25 mg/25 mg.	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088229	Thioridazine HCl Oral Solution USP, 100 mg/mL	Actavis Mid Atlantic, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088563	Thioridazine HCl Tablets USP, 50 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088567	Thioridazine HCl Tablets USP, 25 mg	Do.
ANDA 088733	Meclizine HCl Tablets, 25 mg (Chewable)	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088869	Thioridazine HCl Tablets USP, 150 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 090800	Quinapril Tablets USP, EQ 5 mg base, EQ 10 mg base, EQ 20 mg base, and EQ 40 mg base.	Sun Pharmaceutical Industries, Ltd.
ANDA 091177	Anastrozole Tablets, 1 mg	Do.
ANDA 091466	Letrozole Tablets USP, 2.5 mg	Do.
ANDA 200486	Norethindrone and Ethinyl Estradiol Tablets USP, 0.5 mg/0.035 mg, 0.75 mg/0.035 mg, and 1 mg/0.035 mg.	Mylan Laboratories, Ltd., c/o Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504.
ANDA 200488	Norethindrone and Ethinyl Estradiol Tablets USP, 0.5 mg/0.035 mg.	Do.
ANDA 200489	Norethindrone and Ethinyl Estradiol Tablets USP, 1 mg/0.035 mg.	Do.
ANDA 201250	Vancomycin HCl for Injection USP, EQ 5 g base/vial and EQ 10 g base/vial (Pharmacy Bulk Package).	Teva Pharmaceuticals USA, Inc.
ANDA 201251	Vancomycin HCl for Injection USP, EQ 500 mg base/vial and EQ 1 g base/vial.	Do.
ANDA 201828	Norgestrel and Ethinyl Estradiol Tablets USP, 0.3 mg/0.03 mg.	Mylan Laboratories, Ltd.
ANDA 202203	Topotecan HCl for Injection, EQ 4 mg base/vial	Sun Pharmaceutical Industries, Ltd.
ANDA 202746	Zoledronic Acid Injection, EQ 4 mg base/5 mL	Sun Pharma Global FZE, c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540.
ANDA 202875	Norgestrel and Ethinyl Estradiol Tablets USP, 0.5 mg/0.05 mg.	Mylan Laboratories, Ltd.
ANDA 203476	Zolmitriptan Tablets, 2.5 mg and 5 mg	Sun Pharma Global FZE.
ANDA 203685	Irbesartan Tablets USP, 75 mg, 150 mg, and 300 mg	Ajanta Pharma Ltd., c/o Ajanta Pharma USA, Inc., One Grande Commons, 440 US Highway 22 East, Suite 150, Bridgewater, NJ 08807.
ANDA 203838	Hydrocodone Bitartrate, Chlorpheniramine Maleate, and Pseudoephedrine HCl Oral Solution, 5 mg/4 mg/60 mg per 5 mL.	Tris Pharma, Inc., 2033 Route 130, Monmouth Junction, NJ 08852.
ANDA 203839	Hydrocodone Bitartrate and Pseudoephedrine HCl Oral Solution, 5 mg/60 mg per 5 mL.	Do.

Therefore, approval of the applications listed in table 1 of this document, and all amendments and supplements thereto, is hereby withdrawn as of January 2, 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 table 1 that are in inventory on the date that this notice becomes effective (see the **DATES** section) 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: November 27, 2017.

Leslie Kux,

Associate Commissioner for Policy..

[FR Doc. 2017–25920 Filed 11–30–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Teleconference

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

Dates and Times:

Tuesday, January 9, 2018: 9:00 a.m.–5:30 p.m. ET

Wednesday, January 10, 2018: 8:45 a.m.–3:00 p.m. ET

Place: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW., Rm. 705A, Washington, DC 20201.

Status: Open.

Purpose: At the January 9–10, 2018 full meeting, the Committee will hear presentations, hold discussions on several health data policy topics and begin work on activities outlined in the NCVHS 2018 workplan. An environmental scan report will be reviewed and discussed by the full Committee as part of the Health Information Privacy and Security Beyond HIPAA project. This effort includes an exploration of challenges that extend beyond HIPAA and the range of policy options that may be available to the Department related to privacy, security and access measures to