https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 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: Moon Hee V. Choi, 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: *AADPAC@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 FDA's website 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 committees will be asked to discuss new drug application (NDA) 209257, proposed tradename, HYDEXOR, a fixed-dose combination oral tablet, submitted by Charleston Laboratories, Inc., that contains hydrocodone, acetaminophen, and promethazine, for the short-term management of acute pain severe enough to require an opioid analgesic while preventing and reducing opioid-induced nausea and vomiting. The committees will also be asked to discuss the abuse potential of this non-abuse-deterrent product and whether it should be approved.

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 website 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 website 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 committees. Written submissions may be made to the contact person on or before January 31, 2018. Oral presentations from the public will be scheduled between approximately 10:15 a.m. and 11:15 a.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 January 23, 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 January 24, 2018.

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

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

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 Moon Hee V. Choi 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: December 26, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–28250 Filed 12–29–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6852]

Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc. et al.; Withdrawal of Approval of 111 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 111 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 February 1, 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 table 1 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 040008	Heparin Sodium Injection USP, 1000 units/milliliter (mL)	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 040137	Chlorzoxazone Tablets USP, 500 milligrams (mg)	Do.
ANDA 040410	Methylphenidate Hydrochloride (HCl) Extended-Release Tablets USP, 20 mg.	Do.
ANDA 040456	Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets, 1.25 mg/1.25 mg/1.25 mg/1.25 mg, 2.5 mg/2.5 mg/2.5 mg/2.5 mg, 5 mg/5 mg/5 mg/5 mg, and 7.5 mg/7.5 mg/7.5 mg/7.5 mg.	Actavis Elizabeth, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 040666	A-Hydrocort (hydrocortisone sodium succinate) for Injection USP, Equivalent to (EQ) 100 mg base/vial.	Hospira, Inc., a Pfizer Company, 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045.
ANDA 062520	Kanamycin Sulfate Injection, EQ 1 gram (g) base/3 mL	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 062693	Cephradine for Oral Suspension USP, 125 mg/5 mL and 250 mg/5 mL.	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 062844	Nafcillin for Injection USP, EQ 500 mg base/vial, EQ 1 g base/vial, EQ 1.5 g base/vial, EQ 2 g base/vial, and EQ 4 g base/vial.	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 062856	Oxacillin for Injection USP, EQ 250 mg base/vial, EQ 500 mg base/vial, EQ 1 g base/vial, EQ 2 g base/vial, and EQ 4 g base/vial.	Do.
ANDA 062984	Oxacillin for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package).	Do.
ANDA 062991	Penicillin G Potassium for Injection USP, 1 million units/vial, 5 million units/vial, 10 million units/vial, and 20 million units/vial.	Do.
ANDA 063008	Nafcillin for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package).	Do.
ANDA 063014	Penicillin G Sodium for Injection USP, 5 million units/vial	Do.
ANDA 063106	Gentamicin Injection USP, EQ 40 mg base/mL	Teva Pharmaceuticals USA, Inc.
ANDA 064035	Cefuroxime for Injection USP, EQ 750 mg base/vial and EQ 1.5 g base/vial.	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 065280	Cefazolin for Injection USP, EQ 500 mg base/vial and EQ 1 g base/vial.	Cephazone Pharma, LLC, 250 E. Bonita Ave., Pomona, CA 91767.
ANDA 065294	Ceftriaxone for Injection USP, EQ 250 mg base/vial, EQ 500 mg base/vial, EQ 1 g base/vial, and EQ 2 g base/vial.	Do.
ANDA 065295	Cefazolin for Injection USP, EQ 10 g base/vial (Pharmacy Bulk Package).	Do.
ANDA 065296	Cefazolin for Injection USP, EQ 20 g base/vial (Pharmacy Bulk Package).	Do.
ANDA 070301	Propranolol HCl and Hydrochlorothiazide Tablets USP, 40 mg/25 mg.	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 070305	Propranolol HCl and Hydrochlorothiazide Tablets USP, 80 mg/25 mg.	Do.
ANDA 070468	Verapamil HCl Tablets USP, 120 mg	Actavis Elizabeth, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 070549	Propranolol HCl Tablets USP, 20 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 070703	Methyldopa Tablets USP, 250 mg	Do.
ANDA 070714	Haloperidol Injection USP, EQ 5 mg base/mL	Do.
ANDA 070851	Propranolol HCl and Hydrochlorothiazide Tablets USP, 40 mg/25 mg.	Actavis Elizabeth, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 070852	Propranolol HCl and Hydrochlorothiazide Tablets USP, 80 mg/25 mg.	Do.
ANDA 070855	Verapamil HCl Tablets USP, 80 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 070958	Methyldopa and Hydrochlorothiazide Tablets USP, 250 mg/15 mg.	Do.
ANDA 070959	Methyldopa and Hydrochlorothiazide Tablets USP, 250 mg/25 mg.	Do.
ANDA 070960	Methyldopa and Hydrochlorothiazide Tablets USP, 500 mg/50 mg.	Do.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 071069	Methyldopa and Hydrochlorothiazide Tablets USP, 500 mg/30 mg.	Do.
ANDA 071110	Lorazepam Tablets USP, 2 mg	Do.
ANDA 071117	Lorazepam Tablets USP, 0.5 mg	Do.
ANDA 071118	Lorazepam Tablets USP, 1 mg	Do.
ANDA 071485	Doxepin HCl Capsules USP, EQ 10 mg base	Do.
ANDA 071486	Doxepin HCl Capsules USP, EQ 25 mg base	Do.
ANDA 071666	Ibuprofen Tablets, 400 mg	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 071792	Propranolol HCl Tablets USP, 90 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 071883	Betamethasone Valerate Lotion USP, EQ 0.1% base	Teva Pharmaceuticals USA, Inc.
ANDA 071919	Nalidixic Acid Tablets USP, 1 g	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 071936	Nalidixic Acid Tablets USP, 250 mg	Do.
ANDA 072061	Nalidixic Acid Tablets USP, 500 mg	Do.
ANDA 072164	Maprotiline HCl Tablets USP, 75 mg	Do.
ANDA 072795	Metaproterenol Sulfate Tablets USP, 20 mg	Do.
ANDA 072824	Baclofen Tablets USP, 10 mg	Do.
ANDA 073373	Morphine Sulfate Injection USP, 1 mg/2 mL (Ampule)	Do.
ANDA 073374	Morphine Sulfate Injection USP, 10 mg/10 mL (Ampule)	Do.
ANDA 073375	Morphine Sulfate Injection USP, 5 mg/10 mL (Vial)	Do.
ANDA 073376	Morphine Sulfate Injection USP, 10 mg/10 mL (Vial)	Do.
ANDA 073443	Meperidine HCl Injection USP, 10 mg/mL (Preservative Free)	Do.
ANDA 073444	Meperidine HCl Injection USP, 50 mg/mL	Do.
ANDA 073529	Doxapram HCl Injection USP, 20 mg/mL	Do.
ANDA 074032	Metoprolol Tartrate Injection USP, 1 mg/mL	Do.
ANDA 074195	Naproxen Sodium Tablets USP, EQ 250 mg base and EQ 500 mg base.	Do.
ANDA 074276	Lorazepam Injection USP, 2 mg/mL and 4 mg/mL	Do.
ANDA 074279	Dobutamine Injection USP, EQ 12.5 mg base/mL	Do.
ANDA 074393	Isoflurane USP, 99.9%	Do.
ANDA 074457	Naproxen Tablets USP, 250 mg, 375 mg, and 500 mg	Do.
ANDA 074598	Hydromorphone HCl Injection USP, 10 mg/mL	Hospira, Inc.
ANDA 074864	Ranitidine Tablets USP, EQ 150 mg base and EQ 300 mg base.	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 074906	Acyclovir Capsules USP, 200 mg	Actavis Elizabeth, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 075253	Ticlopidine HCl Tablets, 250 mg	Do.
ANDA 075650	Famotidine Tablets USP, 20 mg and 40 mg	Do.
ANDA 075672	Bisoprolol Fumarate and Hydrochlorothiazide Tablets, 2.5 mg/6.25 mg, 5 mg/6.25 mg, and 10 mg/6.25 mg.	Do.
ANDA 075843	Oxaprozin Tablets, 600 mg	Do.
ANDA 075901	Fluvoxamine Maleate Tablets, 25 mg, 50 mg, and 100 mg	Do.
ANDA 075960	Tramadol HCl Tablets, 50 mg	Do.
ANDA 076689	Mirtazapine Orally Disintegrating Tablets USP, 15 mg, 30 mg, and 45 mg.	Do.
ANDA 077174	Foscarnet Sodium Injection, 2.4 g/100 mL	Hospira, Inc.
ANDA 077963	Granisetron HCl Injection, EQ 1 mg base/mL	Teva Pharmaceuticals USA, Inc.
ANDA 080615	Dimenhydrinate Injection, 50 mg/mL	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 080713	Tripelennamine HCl Tablets USP, 50 mg	Do.
ANDA 081150	Hydroxyzine HCl Tablets USP, 25 mg	Do.
ANDA 081151	Hydroxyzine HCl Tablets USP, 50 mg	Do.
ANDA 083287	Procainamide HCl Capsules USP, 250 mg	Do.
ANDA 084280	Procainamide HCl Capsules USP, 500 mg	Do.
ANDA 084403	Procainamide HCl Capsules USP, 375 mg	Do.
ANDA 084467	Reserpine and Hydrochlorothiazide Tablets USP, 0.125 mg/50 mg.	Do.
ANDA 085083	Diphenhydramine HCl Capsules USP, 50 mg	Do.
ANDA 085140	Quinidine Sulfate Tablets USP, 200 mg	Do.
ANDA 085173	Chlorothiazide Tablets USP, 250 mg	Do.
ANDA 085180	Methocarbamol Tablets USP, 500 mg	Do.
ANDA 085192	Methocarbamol Tablets USP, 750 mg	Do.
ANDA 085597	Methylprednisolone Acetate Injectable Suspension USP, 20 mg/mL.	Do.
ANDA 086013	Statobex (phendimetrazine tartrate) Tablets USP, 35 mg	Teva Pharmaceuticals USA, Inc.
ANDA 086029	Testosterone Cypionate Injection USP, 100 mg/mL	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 086031	Isosorbide Dinitrate Sublingual Tablets USP, 5 mg	Do.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 086034	Isosorbide Dinitrate Tablets USP, 5 mg	Do.
ANDA 086188	Gerimal (ergoloid mesylates) Sublingual Tablets, 1 mg	Do.
ANDA 086385	Nandrolone Decanoate Injection, 50 mg/mL	Do.
ANDA 086562	Wigraine (ergotamine tartrate and caffeine) Tablets USP, 1 mg/100 mg.	Organon USA, Inc., Subsidiary of Merck & Co., Inc., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
ANDA 086742	Choledyl SA (oxtriphylline) Extended-Release Tablets, 600 mg	Warner Chilcott Co., LLC, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 086863	Chlorpromazine HCl Oral Concentrate USP, 100 mg/mL	Actavis Mid Atlantic, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 087233	Ergoloid Mesylates Sublingual Tablets USP, 0.5 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 087244	Ergoloid Mesylates Tablets USP, 1 mg	Do.
ANDA 087318..	Tolbutamide Tablets USP, 500 mg	Do.
ANDA 087727	Aminophylline Oral Solution USP, 105 mg/5 mL (Dye Free)	Actavis Mid Atlantic, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088128	Nandrolone Decanoate Injection, 200 mg/mL	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088337	Ergostat (ergotamine tartrate) Sublingual Tablets USP, 2 mg	Do.
ANDA 088477	Thioridazine HCl Tablets USP, 15 mg	Do.
ANDA 088561	Thioridazine HCl Tablets USP, 10 mg	Do.
ANDA 088564	Thioridazine HCl Tablets USP, 100 mg	Do.
ANDA 088724	Methyclothiazide Tablets USP, 5 mg	Do.
ANDA 088734	Meclizine HCl Tablets, 25 mg	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088769	Mepivacaine HCl Injection USP, 1%	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088770	Mepivacaine HCl Injection USP, 2%	Do.
ANDA 088872	Thioridazine HCl Tablets USP, 200 mg	Do.
ANDA 089026	Procainamide HCl Extended-Release Tablets USP, 250 mg	Do.
ANDA 089027	Procainamide HCl Extended-Release Tablets USP, 500 mg	Do.
ANDA 089530	Prochlorperazine Edisylate Injection USP, EQ 5 mg base/mL	Do.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of February 1, 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 **DATES**) 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: December 26, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–28254 Filed 12–29–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5715]

Watson Laboratories, Inc., and Barr Laboratories, Inc., Subsidiaries of Teva Pharmaceuticals USA, Inc.; Withdrawal of Approval of 54 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of October 24, 2017. The document announced the withdrawal of approval of 54 abbreviated new drug applications (ANDAs) from two applicants, effective November 24, 2017. The notice inadvertently announced the withdrawal of approval for ANDA 087296 for Chlorthalidone Tablets USP, 25 milligrams, held by Watson Laboratories, Inc., a subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044. FDA confirms that the approval of ANDA 087296 is still in effect.

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: In FR Doc. 2017–23046, appearing on page 49214 in the **Federal Register** of Tuesday, October 24, 2017, the following correction is made:

1. On page 49215, in table 1, the entry for ANDA 087296 is removed.

Dated: December 26, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–28253 Filed 12–29–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–1846]

Labeling for Combined Hormonal Contraceptives; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.