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Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of February 1, 2018.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.