Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of February 1, 2018.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, and all amendments and supplements thereto, that are in inventory on the date that inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.


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. 7, 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.


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Labeling for Combined Hormonal Contraceptives; Draft Guidance for Industry; Availability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