This document is scheduled to be published in the
Federal Register on 02/12/2019 and available online at
https://federalregister.gov/d/2019-02032, and on **govinfo.gov**

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0163]

Hospira, Inc., et al.; Withdrawal of Approval of 12 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 12 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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 065343	Epirubicin Hydrochloride (HCl) Injection USP, 10 milligrams (mg)/5 milliliters (mL), 50 mg/25 mL, 150 mg/75 mL, and 200 mg/100 mL	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045
ANDA 070562	Flurazepam HCl Capsules USP, 15 mg	Pharmaceutical Basics, Inc., 301 South Cherokee St., Denver, CO 80223
ANDA 070563	Flurazepam HCl Capsules USP, 30 mg	Do.
ANDA 071808	Flurazepam HCl Capsules USP, 15 mg	Halsey Drug Co., Inc., 1827 Pacific St., Brooklyn, NY 11233
ANDA 071809	Flurazepam HCl Capsules USP, 30 mg	Do.
ANDA 076827	Vinorelbine Injection USP, Equivalent to 10 mg base/mL	Hospira, Inc.
ANDA 077736	Polyethylene Glycol 3350 Powder for Oral Solution, 17 grams/scoopful	Breckenridge Pharmaceutical, Inc., 6111 Broken Sound Parkway NW, suite 170, Boca Raton, FL 33487
ANDA 085763	Glutethimide Tablets, 500 mg	Chelsea Laboratories, Inc., 896 Orlando Ave., West Hampstead, NY 11552
ANDA 085791	Pentobarbital Sodium Capsules, 100 mg	Do.
ANDA 087297	Glutethimide Tablets, 500 mg	Phoenix Pharmaceuticals, Inc., 111 Leuning St., South Hackensack, NJ 07606
ANDA 088819	Aristocort A (triamcinolone acetonide) Cream, 0.1%	Astellas Pharma U.S., Inc., Three Parkway North, Deerfield, IL 60015
ANDA 089459	Glutethimide Tablets, 500 mg	Halsey Drug Co., Inc.

Therefore, approval of the applications listed in the table and all amendments and supplements thereto, are hereby withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. 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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** 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: February 7, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019-02032 Filed: 2/11/2019 8:45 am; Publication Date: 2/12/2019]