



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0002]

Hospira, Inc. et al.; Withdrawal of Approval of 44 New Drug Applications and 158 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 4, 2016 (81 FR 68427). The document announced the withdrawal of approval of 44 new drug applications and 158 abbreviated new drug applications (ANDAs) from multiple applicants, effective November 3, 2016. The document inadvertently announced withdrawal of approval for the following two ANDAs: ANDA 074123 for Pindolol Tablets, held by G&W Laboratories, Inc., 111 Coolidge St., South Plainfield, NJ 07080; and ANDA 080828 for Hydrocortisone Acetate Ophthalmic Ointment USP, held by Fera Pharmaceuticals LLC, 134 Birch Hill Rd., Locust Valley, NY 11560. FDA confirms that the approval of ANDAs 074123 and 080828 is still in effect.

FOR FURTHER INFORMATION CONTACT: Florine Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6248, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: In the Federal Register of Tuesday, October 4, 2016, appearing on page 68427 in FR Doc. 2016-23893, the following corrections are made:

1. On page 68429, in table 1, the entry for ANDA 074123 is removed.

2. On page 68431, in table 1, the entry for ANDA 080828 is removed.

Dated: July 12, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-15003 Filed: 7/17/2017 8:45 am; Publication Date: 7/18/2017]