



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 erroneously included abbreviated new drug application (ANDA) 075726 for Pemoline Tablets, 18.75 milligrams (mg), 37.5 mg, and 75 mg, held by Mallinkrodt Pharmaceuticals, LLC. This notice corrects that error.

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 correction is made:

1. On page 68430, in table 1, the entry for ANDA 075726 is removed.

In a separate notice published in this issue of the *Federal Register*, FDA is withdrawing the approval of ANDA 075726 under 21 CFR 314.150(d).

Dated: February 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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