4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3432]

Organon USA et al.; Withdrawal of Approval of 67 New Drug Applications and 128 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 13, 2015 (80 FR 61426). The document announced the withdrawal of approval of 67 new drug applications (NDAs) and 128 abbreviated new drug applications from multiple applicants, effective November 12, 2015. The document indicated that FDA was withdrawing approval of the following two NDAs after receiving a request from the NDA holder, Merck Sharp & Dohme Corp. (Merck), 1 Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889: NDA 016096, MINTEZOL (thiabendazole) Tablets, and NDA 016097, MINTEZOL (thiabendazole) Oral Suspension. Before withdrawal of these NDAs became effective, Merck informed FDA that it did not want approval of the NDAs withdrawn. Because Merck timely requested that approval of these NDAs not be withdrawn, the approval of NDAs 016096 and 016097 is still in effect.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. 6366, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: In the Federal Register of Tuesday, October 13, 2015, appearing on page 61426 in FR Doc. 2015-25922, the following correction is made:

On page 61426, in table 1, the entries for NDAs 016096 and 016097 are removed.

Dated: May 31, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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