4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-1707]

Teva Pharmaceuticals USA, Inc., et al.; Withdrawal of Approval of Five Abbreviated New Drug Applications for Pemoline Products; 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 June 4, 2019. That notice, withdrawing approval of five abbreviated new drug applications for pemoline products, contained an incorrect website address for an archived web page of a *Postmarket Drug Safety Information for Healthcare Professionals* communication that FDA issued on October 24, 2005, stating its conclusion that the overall liver toxicity risk of CYLERT (new drug applications 016832 and 017703) and generic pemoline products outweighed the benefits of these products. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of June 4, 2019 (84 FR 25811), appearing on page 25811 in FR Doc. 2019-11519, the following correction is made:

On page 25811, in the last paragraph of the third column, the website address, https://wayback.archive-it.org/7993/20171114124349/https://www.fda.gov/DrugsDrugSafety/PostmarketDrugSafetyinformationforPatientsandProviders/ucm126461.htm, is corrected to read

https://wayback.archive-it.org/7993/20171114124349/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126461.htm.

Dated: September 27, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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