



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0409]

Mallinkrodt Pharmaceuticals LLC; Withdrawal of Approval of an Abbreviated New Drug Application for PEMOLINE Tablets, 18.75 Milligrams, 37.5 Milligrams, and 75 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the approval of abbreviated new drug application (ANDA) 075726 for PEMOLINE Tablets, 18.75 milligrams (mg), 37.5 mg, and 75 mg, held by Mallinkrodt Pharmaceuticals, LLC (Mallinkrodt).

Mallinkrodt requested withdrawal of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Kristiana Brugger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6262, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION: FDA approved ANDA 075726 for PEMOLINE Tablets, 18.75 mg, 37.5 mg, and 75 mg, on March 30, 2001, for the conditions of use in the labeling of new drug application (NDA) 016832, the reference listed drug on which it relied. However, on October 24, 2005, FDA announced its concern that the overall liver toxicity risk of CYLERT (NDA 016832) and generic pemoline products outweighed the benefits of these

products. Mallinkrodt and other holders of approved applications for PEMOLINE products ceased marketing them at that time. Indeed, Mallinkrodt stated in its May 15, 2013, request for withdrawal of approval of ANDA 075726 that it had never manufactured or distributed its product after it received approval of its application.

In the *Federal Register* of October 4, 2016 (81 FR 68427), FDA erroneously included ANDA 075726 in a list of drug applications for which approval was being withdrawn under § 314.150(c) (21 CFR 314.150(c)). In a separate notice published in this issue of the *Federal Register*, FDA corrects that notice to remove ANDA 075726 from the list of applications whose approval was withdrawn under § 314.150(c). In addition, for the reasons discussed above, and pursuant to Mallinkrodt's request, FDA is withdrawing approval of ANDA 075726, and all amendments and supplements thereto, under § 314.150(d). Distribution of PEMOLINE Tablets, 18.75 mg, 37.5 mg, and 75 mg, in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: February 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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