4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0680]

Fosun Pharma USA Inc.; Withdrawal of Approval of 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 or Agency) is withdrawing approval of abbreviated new drug application (ANDA) 075286 for pemoline tablets, 18.75 milligrams (mg), 37.5 mg, and 75 mg, held by Fosun Pharma USA Inc. (Fosun), 104 Carnegie Center, Princeton, NJ 08540. Fosun requested that approval of this application be withdrawn and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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: Kimberly Lehrfeld, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On June 30, 1999, FDA approved ANDA 075286 for pemoline tablets, 18.75 mg, 37.5 mg, and 75 mg, for the conditions of use in the labeling of new drug application (NDA) 016832, the reference listed drug on which it relied. On October 24, 2005, the Agency issued a Postmarket Drug Safety Information for Patients and Providers communication entitled "Information for Healthcare Professionals: Pemoline Tablets and Chewable Tablets (Marketed as CYLERT)" which concluded the overall liver toxicity risk of CYLERT (pemoline) (NDAs 016832 and 017703) and generic pemoline products outweighed

the benefits of these products (https://wayback.archive-it.org/7993/20171114124349/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126461.htm).

All holders of approved applications for pemoline products, including Fosun, ceased marketing the products at that time. On April 22, 2019, Fosun requested that FDA withdraw approval of ANDA 075286, pursuant to § 314.150(d) (21 CFR 314.150(d)) and waived its opportunity for a hearing.

For the reasons discussed above, and in accordance with the applicant's request, approval of ANDA 075286 for pemoline tablets, 18.75 mg, 37.5 mg, and 75 mg, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of pemoline tablets, 18.75 mg, 37.5 mg, and 75 mg, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d))).

Dated: March 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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