4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-2008]

Vintage Pharmaceuticals; 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) 075328 for pemoline tablets, 18.75 milligrams (mg), 37.5 mg, and 75 mg, held by Vintage Pharmaceuticals, 120 Vintage Dr., Huntsville, AL 35811 (Vintage). Vintage requested that approval of this application be withdrawn and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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, 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 April 19, 2000, FDA approved ANDA 075328 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 Vintage, ceased marketing the products at that time. On June 21, 2012, Vintage requested that FDA withdraw approval of ANDA 075328, pursuant to § 314.150(d) (21 CFR 314.150(d)) and waived its opportunity for a hearing. Vintage stated in its June 21, 2012, request for withdrawal of approval of ANDA 075328 that it had discontinued manufacturing the product since April 2005.

In the *Federal Register* issue of July 19, 2013 (78 FR 43210), FDA erroneously included ANDA 075328 in a list of drug applications for which approval was being withdrawn under § 314.150(c). In a separate notice published in this issue of the *Federal Register*, FDA corrected the July 19, 2013, notice to remove ANDA 075328 from the list of applications whose approval was withdrawn under § 314.150(c).

For the reasons discussed above, and in accordance with the applicant's request, approval of ANDA 075328 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: May 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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