4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0687]

Abbott Laboratories Pharmaceutical Products Division; Withdrawal of Approval of New Drug Applications for CYLERT (Pemoline) Tablets, 18.75 Milligrams, 37.5 Milligrams, and 75 Milligrams, and CYLERT (Pemoline) Chewable Tablets, 37.5 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of new drug application (NDA) 016832 for CYCLERT (pemoline) tablets, 18.75 milligrams (mg), 37.5 mg, and 75 mg, as well as NDA 017703 for CYCLERT (pemoline) chewable tablets, 37.5 mg, held by Abbott Laboratories Pharmaceutical Products Division, c/o G&L Scientific, 25 Independence Blvd., 4th Floor, Warren, NJ 07059 (Abbott). Abbott requested that approval of these applications be withdrawn and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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 January 27, 1975, FDA approved NDA 016832 for CYLERT (pemoline) tablets, 18.75 mg, 37.5 mg, and 75 mg, for use in the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD). On January 30, 1976, the Agency approved NDA 017703 for CYLERT (pemoline) chewable tablets, 37.5 mg, for use in the treatment of ADHD. On October 24, 2005, FDA 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 Abbott, ceased marketing the products at that time. On April 12, 2021, FDA contacted Abbott and requested the company submit a request for FDA to withdraw approval of NDAs 016832 and 017703 for CYLERT tablets and CYLERT chewable tablets, respectively, pursuant to § 314.150(d) (21 CFR 314.150(d)) due to the risk of liver toxicity. On September 2, 2021, Abbott requested that FDA withdraw approval of CYLERT (pemoline) tablets and CYLERT (pemoline) chewable tablets, NDAs 016832 and 017703, respectively, under § 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 NDAs 016832 and 017703 for CYLERT (pemoline) tablets, 18.75 mg, 37.5 mg, and 75 mg, and CYLERT (pemoline) chewable tablets, 37.5 mg, respectively, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of CYLERT (pemoline) tablets, 18.75 mg, 37.5 mg, and 75 mg, and CYLERT (pemoline) chewable tablets, 37.5 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 (FD&C Act) (21 U.S.C. 355(a) and 331(d))).

Dated: May 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-10924 Filed: 5/22/2023 8:45 am; Publication Date: 5/23/2023]