ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Individuals (male and female) aged 18 years and older	Study Screener	30,880	1	2/60
	Survey Module	5,445	1	30/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2023–10957 Filed 5–22–23; 8:45 am]

BILLING CODE 4163–18–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 Abbott requested that approval of these applications be withdrawn and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of May 23, 2023.

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 5–22–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Nurse Faculty Loan Program—Program Specific Data Form, Annual Performance Report Financial Data Form and NFLP Due Diligence Form; OMB No. 0915–0314–Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than June 22, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information