TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]—Continued

21 CFR section	Form FDA No./description	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1210.23	1815/Permits granted on certificates	1	1	1	0.5 (30 minutes)	1
Total	.....	.....	.....	.....	.....	306

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

21 CFR section/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1210.15/Pasteurization records	1	1	1	0.05 (3 minutes)	1

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

The Secretary of Health and Human Services has the discretion to allow Form FDA 1815, a duly certified statement signed by an accredited official of a foreign government, to be submitted in lieu of Forms FDA 1994 and 1995. In the past, Form FDA 1815 has been submitted in lieu of these forms. Because we have not received any Forms FDA 1994 or 1995 in the last 3 years, we assume no more than one will be submitted annually.

No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by us (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product, shipper's name and address). Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not subject to review by OMB under the PRA. Under 5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of business activities.

Based on a review of the information collection since our last OMB approval, we have retained our burden estimate. The estimated number of respondents and hours per response are based on our experience with the import milk permit program and the average number of import milk permit holders over the past 3 years. However, we have not received any responses in the last 3 years; therefore, we estimate that one or fewer to be submitted annually. Although we have not received any responses in the last 3 years, we believe these information collection provisions should be extended to provide for the potential future need for a milk importer.

Dated: March 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06028 Filed 3–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0644]

Eli Lilly and Company; Withdrawal of Approval of SARAFEM (Fluoxetine Hydrochloride) Capsules, Equivalent to 10 Milligrams Base and Equivalent to 20 Milligrams Base, Including the Premenstrual Dysphoric Disorder Indication Approved Under New Drug Application 018936

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of SARAFEM (fluoxetine hydrochloride (HCl)) capsules, equivalent to (EQ) 10 milligrams (mg) base and EQ 20 mg base, including the premenstrual dysphoric disorder (PMDD) indication, approved under new drug application (NDA) 018936. This NDA is held by Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285 (Lilly). Lilly notified the Agency in writing that SARAFEM (fluoxetine HCl) capsules, EQ 10 mg base and EQ 20 mg base, indicated for the treatment of PMDD, was no longer marketed and requested that the approval of SARAFEM (fluoxetine HCl) capsules, including the PMDD indication, be withdrawn.

DATES: Approval is withdrawn as of April 22, 2024.

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 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On December 29, 1987, FDA approved NDA 018936 for PROZAC (fluoxetine HCl) capsules, EQ 20 mg base, for major depressive disorder. On July 6, 2000, FDA approved a supplement to NDA 018936 for SARAFEM (fluoxetine HCl) capsules, EQ 10 mg base and EQ 20 mg base, indicated for the treatment of PMDD. SARAFEM (fluoxetine HCl) capsules are only approved for the PMDD indication. SARAFEM (fluoxetine HCl) capsules and PROZAC (fluoxetine HCl) capsules, EQ 10 mg base and EQ 20 mg base, were marketed by Lilly under the same NDA with distinct labeling, including distinct Prescribing Information, carton and container labels, and labeling for patients and caregivers.

On June 10, 2010, Lilly informed FDA that it had discontinued marketing of SARAFEM (fluoxetine HCl) capsules, EQ 10 mg base and EQ 20 mg base. On August 4, 2023, Lilly requested, in writing, that FDA withdraw approval of SARAFEM (fluoxetine HCl) capsules, EQ 10 mg base and EQ 20 mg base, including the PMDD indication, under § 314.150(c) (21 CFR 314.150(c)). Lilly also waived its opportunity for a

hearing. Withdrawal of approval of an application under § 314.150(c) is without prejudice to refiling.

Therefore, approval of SARAFEM (fluoxetine HCl) capsules, EQ 10 mg base and EQ 20 mg base, including the PMDD indication approved under NDA 018936, is hereby withdrawn as of April 22, 2024. Withdrawal of approval of SARAFEM (fluoxetine HCl) capsules, EQ 10 mg base and EQ 20 mg base, including the PMDD indication approved under NDA 018936, does not affect approval of PROZAC (fluoxetine HCl) capsules, EQ 10 mg base, EQ 20 mg base, EQ 40 mg base, and EQ 60 mg base, or any other indication approved under NDA 018936. Introduction or delivery for introduction into interstate commerce of SARAFEM (fluoxetine HCl) capsules, EQ 10 mg base and EQ 20 mg base, without an approved NDA violates 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 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05982 Filed 3–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Vascular Biology and Pathophysiology.

Date: April 12, 2024.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Vivian Tang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–6208, *tangvw@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–22–233: Time-Sensitive Opportunities for Health Research.

Date: April 12, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Wenjuan Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 3154, Bethesda, MD 20892, (301) 480–8667, *wangw22@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cancer Biology.

Date: April 12, 2024.

Time: 12:00 p.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Amy L. Rubinstein, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5152, MSC 7844, Bethesda, MD 20892, 301–408–9754, *rubinsteinal@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA: Public Health Communication Messaging about the Continuum of Risk for Tobacco Products.

Date: April 15, 2024.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Pamela Jeter, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 10J08, Bethesda, MD 20892, (301) 827–6401, *pamela.jeter@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Basic Cancer Immunology.

Date: April 17, 2024.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sarita Kandula Sastry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20782, 301–402–4788, *sarita.sastry@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 18, 2024.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–06011 Filed 3–20–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Drug Discovery and Molecular Pharmacology.

Date: April 2, 2024.

Time: 1:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jeffrey Smiley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, (301) 272–4596, *smileyja@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 18, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–06002 Filed 3–20–24; 8:45 am]

BILLING CODE 4140–01–P