such records must be made available for inspection and copying by FDA upon request (§ 558.6(c)(4)). These record requirements are currently approved under OMB control number 0910–0152, ''Current Good Manufacturing Practice Regulations for Medicated Feed.''

C. Third-Party Disclosure Requirements

Description of Respondents: Food Animal Veterinarians, VFD Feed Distributors, and Clients.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR part/activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
558.6(b)(3)(v) and (b)(7)(ix); requires veterinarians to disclose information on a VFD	5,278	40	211,120	0.12 (7 minutes)	25,334
558.6(c)(8); requires acknowledgment letter from one distributor to another	2,422	5	12,110	0.12 (7 minutes)	1,453
Total	7,700				26,787

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on program experience, we believe the original number of third-party disclosures estimate was too high and have decreased the number of disclosures per respondent. The VFD regulation also contains several labeling provisions. These labeling statements are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and therefore do not constitute a ''collection of information'' under the PRA (44 U.S.C. 3501, *et seq.*).

After a review of the information collection since our last request for OMB approval, we have adjusted our estimates based on our experience with the VFD regulations and updated data. As a result, the total burden for the information collection has decreased 39,387 hours since the last OMB approval.

Dated: March 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05986 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–0972]

Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations Under the Federal Import Milk Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting and recordkeeping requirements of our regulations implementing the Federal Import Milk Act (FIMA).

DATES: Either electronic or written comments on the collection of information must be submitted by May 20, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 20, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–0972 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations Under the Federal Import Milk Act.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including

the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Regulations Under the Federal Import Milk Act (FIMA)—21 CFR Part 1210

OMB Control Number 0910–0212—Extension

This information collection supports FDA regulations. Under FIMA (21 U.S.C. 141–149), milk or cream may be imported into the United States only by the holder of a valid import milk permit (21 U.S.C. 141). Before such permit is issued: (1) all cows from which import milk or cream is produced must be physically examined and found healthy; (2) if the milk or cream is imported raw, all such cows must pass a tuberculin test; (3) the dairy farm and each plant in which the milk or cream is processed or handled must be inspected and found to meet certain sanitary requirements; (4) bacterial counts of the milk at the time of importation must not exceed specified limits; and (5) the temperature of the milk or cream at time of importation must not exceed 50 °F (21 U.S.C. 142).

Our regulations in part 1210 (21 CFR part 1210) implement the provisions of FIMA. Sections 1210.11 and 1210.14 require reports on the sanitary conditions of, respectively, dairy farms and plants producing milk and/or cream to be shipped to the United States. Section 1210.12 requires reports on the physical examination of herds, while § 1210.13 requires the reporting of tuberculin testing of the herds. In addition, the regulations in part 1210 require that dairy farmers and plants maintain pasteurization records (§ 1210.15) and that each container of milk or cream imported into the United States bear a tag with the product type, permit number, and shipper's name and address (§ 1210.22). Section 1210.20 requires that an application for a permit to ship or transport milk or cream into the United States be made by the actual shipper. Section 1210.23 allows permits to be granted based on certificates from accredited officials.

To assist respondents with the regulatory requirements, we have developed the following forms:

- Form FDA 1815: Certificate/Transmittal for an Application (21 CFR 1210.23).
- Form FDA 1993: Application for Permit To Ship or Transport Milk and/or Cream into the United States (21 CFR 1210.20).
- Form FDA 1994: Report of Tuberculin Tests of Cattle (21 CFR 1210.13).
- Form FDA 1995: Report of Physical Examination of Cows (21 CFR 1210.12).
- Form FDA 1996: Dairy Farm Sanitary Report (21 CFR 1210.11).
- Form FDA 1997: Score Card for Sanitary Inspection of Milk Plants (21 CFR 1210.14).

The information collected is used by FDA to determine whether a permit to import milk and/or cream into the United States should be granted.

Description of Respondents: Respondents include foreign dairy farms and plants engaged in transporting milk and/or cream into the United States. Respondents are from the private sector (for-profit businesses).

We estimate the burden of this collection of information as follows:

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

21 CFR section	Form FDA No./description	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1210.11	1996/Sanitary inspection of dairy farms	1	200	200	1.5	300
1210.12	1995/Physical examination of cows	1	1	1	0.5 (30 minutes)	1
1210.13	1994/Tuberculin test	1	1	1	0.5 (30 minutes)	1
1210.14	1997/Sanitary inspections of plants	1	1	1	2.0	2
1210.20	1993/Application for permit	1	1	1	0.5 (30 minutes)	1

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