DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2019–N–5666, FDA–2011–N–0231, FDA–2010–N–0161, FDA–2011–N–0275, and FDA–2013–D–0575]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *http://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Empirical Study of Promotional Implications of Proprietary Prescription Drug Names	0910–0896	4/30/2023
Adverse Experience Reporting for Licensed Biological Products; and General Records	0910–0308	4/30/2024
Export Certificates for FDA Regulated Products	0910–0498	4/30/2024
Certification to Accompany Drug, Biological Product, and Device Applications or Submissions	0910–0616	4/30/2024
Expedited Program for Serious Conditions-Drugs and Biologics	0910–0765	4/30/2024

Dated: May 14, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–10535 Filed 5–18–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–P–2244 and FDA–2020–P–2245]

Determination That ISOPTIN (Verapamil Hydrochloride) Tablets 40 Milligrams, 80 Milligrams, and 120 Milligrams, and CALAN (Verapamil Hydrochloride) Tablets, 40 Milligrams, 80 Milligrams, 120 Milligrams, and 160 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that ISOPTIN (verapamil hydrochloride) tablets, 40 milligrams (mg), 80 mg, and 120 mg, and CALAN (verapamil hydrochloride) tablets, 40 mg, 80 mg, 120 mg, and 160 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for ISOPTIN (verapamil hydrochloride) tablets, 40 mg, 80 mg, and 120 mg, and CALAN (verapamil hydrochloride) tablets, 40 mg, 80 mg, 120 mg, and 160 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6280, Silver Spring, MD 20993–0002, 301–796–3601, *Nicole.Mueller@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ISOPTIN (verapamil hydrochloride) tablets, 40 mg, 80 mg, and 120 mg, are the subject of NDA 018593, held by Mt. Adams Technologies, LLC, and initially approved on March 8, 1982. CALAN (verapamil hydrochloride) tablets, 40 mg, 80 mg, 120 mg, and 160 mg, are the subject of NDA 018817, held by Pfizer Inc., and initially approved on September 10, 1984. ISOPTIN and CALAN are indicated for the treatment of angina, arrythmias, and essential hypertension.

Center Laboratories, Inc., submitted two citizen petitions dated November 30, 2020 (Docket Nos. FDA–2020–P–2244 and FDA–2020–P–2245), under 21 CFR 10.30, requesting that the Agency determine whether ISOPTIN (verapamil hydrochloride) tablets, 40 mg, 80 mg,

and 120 mg, and CALAN (verapamil hydrochloride) tablets, 40 mg, 80 mg, 120 mg, and 160 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petitions and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ISOPTIN (verapamil hydrochloride) tablets, 40 mg, 80 mg, and 120 mg, and CALAN (verapamil hydrochloride) tablets, 40 mg, 80 mg, 120 mg, and 160 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ISOPTIN (verapamil hydrochloride) tablets, 40 mg, 80 mg, and 120 mg, and CALAN (verapamil hydrochloride) tablets, 40 mg, 80 mg, 120 mg, and 160 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ISOPTIN (verapamil hydrochloride) tablets, 40 mg, 80 mg, and 120 mg, and CALAN (verapamil hydrochloride) tablets, 40 mg, 80 mg, 120 mg, and 160 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ISOPTIN (verapamil hydrochloride) tablets, 40 mg, 80 mg, and 120 mg, and CALAN (verapamil hydrochloride) tablets, 40 mg, 80 mg, 120 mg, and 160 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to ISOPTIN (verapamil hydrochloride) tablets, 40 mg, 80 mg, and 120 mg, and CALAN (verapamil hydrochloride) tablets, 40 mg, 80 mg, 120 mg, and 160 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 7, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–10552 Filed 5–18–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Evaluation of Office of Acquisitions System (OASYS) and FFRDC Contract Administration System (FCAS) Vendor Portals National Cancer Institute (NCI)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Marla Jacobson, 9609 Medical Center Drive, MSC 9742, Rockville, MD 20850 or call non-toll-free number 240–276–5267 or Email your request, including your address to: *marla.jacobson@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 minimizes the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Evaluation of Office of Acquisitions System (OASYS) and FFRDC Contract Administration System (FCAS) Vendor Portals National Cancer Institute (NCI), 0925–NEW, Expiration Date XX/XX/XXXX, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Cancer Institute (NCI) Office of Acquisitions (OA), located within the Office of the Director (OD) in the Office of Management (OM) at the National Cancer Institute (NCI), awards and administers contracts and simplified acquisitions in support of the Institute's mission to prevent, diagnose and treat cancer. During the acquisition process, the OA ensures that customer service is paramount, and communications are open and continuous. Currently requests and correspondence are sent to and received from vendors through email with the exception of the FFRDC Contractor who submits through the FCAS Vendor Portal which is in production. To streamline processes, increase transparency and gain efficiencies, the OA developed OASYS and FCAS vendor portals to replace processes that are handled through email (future OASYS Vendor Portal Users) and were (current FCAS Vendor Portal Users) to individual OA recipients. The FCAS Vendor Portal and in the future, the OASYS Vendor Portal will serve as a one-stop shop for transmission of requests, reports, deliverables and other correspondence due on numerous research and development, in support of R&D contracts as well as those contract vehicles awarded using various Federal Acquisition Procedures including but not limited to FAR Part 8, Required Sources of Supplies and Services, FAR Part 13, Simplified Acquisition Procedures, and FAR Part 12, Acquisition of Commercial Items. These reports and deliverables cover a wide variety of topics in the areas of cancer research including prevention, detection, diagnosis, and control.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 12,120.