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.

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CALAN (Verapamil Hydrochloride) Tablets, 40 Milligrams, 80 Milligrams, 120 Milligrams, and 160 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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