comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0449. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Postmarket Surveillance—21 CFR Part 822—OMB Control Number 0910–0449—Extension

Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) authorizes FDA to require a manufacturer to conduct postmarket surveillance (PS) of any device that meets the criteria set forth in the statute. The PS regulation establishes procedures that FDA uses to approve and disapprove PS plans. The regulation provides instructions to manufacturers so they know what information is required in a PS plan submission. FDA reviews PS plan submissions in accordance with part 822 (21 CFR part 822) in §§ 822.15 through 822.19 of the regulation, which describe the grounds for approving or disapproving a PS plan. In addition, the PS regulation provides instructions to manufacturers to submit interim and final reports in accordance with § 822.38. Respondents to this collection of information are those manufacturers who require postmarket surveillance of their products.

In the **Federal Register** of April 28, 2016 (81 FR 25409), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Postmarket surveillance submission (§§ 822.9 and 822.10)	131	1	131	120	15,720
Changes to PS plan after approval (§ 822.21)	15	1	15	40	600
Changes to PS plan for a device that is no longer marketed (§ 822.28)	80	1	80	8	640
Waiver (§ 822.29)	1	1	1	40	40
Exemption request (§ 822.30)	16	1	16	40	640
Periodic reports (§ 822.38)	131	3	393	40	15,720
Total					33,360

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

Explanation of Reporting Burden Estimate: The burden captured in table 1 of this document is based on the data from FDA's internal tracking system. Sections 822.26, 822.27, and 822.34 do not constitute information collection subject to review under the PRA because it entails no burden other than that necessary to identify the respondent, the date, the respondents address, and the nature of the instrument (See 5 CFR 1320.3(h)(1)).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Manufacturer records (§ 822.31)	131	1	131	20	2,620
Investigator records (§ 822.32)	393	1	393	5	1,965
Total					4,585

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

Explanation of Recordkeeping Burden Estimate: FDA expects that at least some of the manufacturers will be able to satisfy the PS requirement using information or data they already have. For purposes of calculating burden, however, FDA has assumed that each PS order can only be satisfied by a 3-year clinically based surveillance plan, using three investigators. These estimates are based on FDA's knowledge and experience with postmarket surveillance.

Dated: September 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21554 Filed 9–7–16; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–P–1037]

Determination That PREVACID IV (Lansoprazole) Intravenous Injection, 30 Milligrams/Vial, Was 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 or Agency) has determined that PREVACID IV (lansoprazole) intravenous injection, 30 milligrams (mg)/vial, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for lansoprazole intravenous injection, 30 mg/vial, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Bronwen Blass, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6224, Silver Spring, MD 20993–0002, 301–796–5092, *Bronwen.blass@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.

PREVACID IV (lansoprazole) intravenous injection, 30 mg/vial, is the subject of NDA 021566, held by Takeda Pharmaceuticals North America, Inc., and initially approved on May 27, 2004. The Indications and Usage section of the PREVACID IV labeling states the following: ''When patients are unable to take the oral formulations, PREVACID I.V. for Injection is indicated as an alternative for the short-term treatment (up to 7 days) of all grades of erosive esophagitis. Once the patient is able to take medications orally, therapy can be switched to an oral formulation of PREVACID for a total of 6 to 8 weeks. The safety and efficacy of PREVACID I.V. for Injection as an initial treatment of erosive esophagitis have not been demonstrated. Refer to full prescribing information for the oral formulations of PREVACID.''

In a letter dated February 5, 2007, Takeda Pharmaceuticals North America, Inc. notified FDA that PREVACID IV (lansoprazole) intravenous injection, 30 mg/vial, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Rose Zhao submitted a citizen petition dated March 18, 2016 (Docket No. FDA–2016–P–1037), under 21 CFR 10.30, requesting that the Agency determine whether PREVACID IV (lansoprazole) intravenous injection, 30 mg/vial, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that PREVACID IV (lansoprazole) intravenous injection, 30 mg/vial, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that PREVACID IV (lansoprazole) intravenous injection, 30 mg/vial, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PREVACID IV (lansoprazole) intravenous injection, 30 mg/vial, 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 this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PREVACID IV (lansoprazole) intravenous injection, 30 mg/vial, 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 PREVACID IV (lansoprazole) intravenous injection, 30 mg/vial, 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 this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: September 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21551 Filed 9–7–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2544]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device: Current Good Manufacturing Practice Quality System Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 recordkeeping requirements related to the medical devices current good manufacturing practice (CGMP) quality system (QS) regulation (CGMP/QS regulation).

DATES: Submit either electronic or written comments on the collection of information by November 7, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way: