ICH was organized to provide an opportunity for harmonization among regulatory Agencies. In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory Agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products for human use among regulators around the world. The six founding members of the ICH are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; CBER and CBER, FDA; and the Pharmaceutical Research and Manufacturers of America. The Standing Members of the ICH Association include Health Canada and Swissmedic. Any party eligible as a Member in accordance with the ICH Articles of Association can apply for membership in writing to the ICH Secretariat. The ICH Secretariat, which coordinates the preparation of documentation, operates as an international nonprofit organization and is funded by the Members of the ICH Association.

The ICH Assembly is the overarching body of the Association and includes representatives from each of the ICH member countries. In May 2016, the ICH Assembly endorsed the draft guidance entitled “ICH S3A Guidance: Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies—Questions and Answers.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access


Dated: September 1, 2016.

Leslie Kux, Associate Commissioner for Policy.

[FR Doc. 2016–21552 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–2013–N–0557]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarket Surveillance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 11, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written
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. 360i) 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

<table>
<thead>
<tr>
<th>Activity/21 CFR section</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postmarket surveillance submission (§§ 822.9 and 822.10)</td>
<td>131</td>
<td>1</td>
<td>131</td>
<td>120</td>
<td>4,585</td>
</tr>
<tr>
<td>Changes to PS plan after approval (§ 822.21)</td>
<td>15</td>
<td>1</td>
<td>15</td>
<td>40</td>
<td>600</td>
</tr>
<tr>
<td>Changes to PS plan for a device that is no longer marketed (§ 822.26)</td>
<td>80</td>
<td>1</td>
<td>80</td>
<td>8</td>
<td>640</td>
</tr>
<tr>
<td>Waiver (§ 822.29)</td>
<td>16</td>
<td>1</td>
<td>16</td>
<td>40</td>
<td>640</td>
</tr>
<tr>
<td>Exemption request (§ 822.30)</td>
<td>16</td>
<td>1</td>
<td>16</td>
<td>40</td>
<td>640</td>
</tr>
<tr>
<td>Periodic reports (§ 822.38)</td>
<td>131</td>
<td>3</td>
<td>393</td>
<td>40</td>
<td>15,720</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,965</strong></td>
<td><strong>1,965</strong></td>
<td><strong>1,965</strong></td>
<td><strong>1,965</strong></td>
<td></td>
</tr>
</tbody>
</table>

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 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

<table>
<thead>
<tr>
<th>Activity/21 CFR section</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer records (§ 822.31)</td>
<td>131</td>
<td>1</td>
<td>131</td>
<td>20</td>
<td>2,620</td>
</tr>
<tr>
<td>Investigator records (§ 822.32)</td>
<td>393</td>
<td>1</td>
<td>393</td>
<td>5</td>
<td>1,965</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,965</strong></td>
<td><strong>1,965</strong></td>
<td><strong>1,965</strong></td>
<td><strong>1,965</strong></td>
<td></td>
</tr>
</tbody>
</table>

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.

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.