part 820 have been approved under OMB control number 0910–0073. In the Federal Register of October 19, 2015 (80 FR 63230), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

<table>
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<th>Total annual records</th>
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<td>20</td>
<td>15</td>
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</table>

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

Dated: March 18, 2016.

Leslie Kux, Associate Commissioner for Policy.

[FR Doc. 2016–06710 Filed 3–23–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–P–0159]

Medical Devices; Exemption From Premarket Notification: Method, Metallic Reduction, Glucose (Urinary, Non-Quantitative) Test System in a Reagent Tablet Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has received a petition requesting exemption from the premarket notification requirements for a method, metallic reduction, glucose (urinary, non-quantitative) test system in a reagent tablet format that is intended to measure glucosuria (glucose in urine). Method, metallic reduction, glucose (urinary, non-quantitative) test systems in a reagent tablet format are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, hypoglycemia, and hyperglycemia. FDA is publishing this notice to obtain comments in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit either electronic or written comments by April 25, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:


Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

· For written/paper comments submitted to the Division of Dockets Management, 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–2016–P–0159 for “Medical Devices; Exemption From Premarket Notification: Method, Metallic Reduction, Glucose (Urinary, Non-Quantitative) Test System in a Reagent Tablet Format.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

· 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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 docket, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ana Loloei Marsal, Center for Devices and Radiological Health (CDRH), Food and
Act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105–115). Section 206 of FDAMA, in part, added a new section, 510(m), to the FD&C Act. Section 510(m)(1) of the FD&C Act requires FDA, within 60 days after enactment of FDAMA, to publish in the Federal Register a list of each type of class II device that does not require a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. Section 510(m)(2) of the FD&C Act provides that 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the Federal Register a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the Federal Register its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the Agency issued on February 19, 1998 entitled “Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff” (Ref. 1).

III. Proposed Class II Device Exemptions

FDA has received the following petition requesting an exemption from premarket notification for a class II device: Evelyn Mirza, Biorex Labs, LLC, 194 E. Wallings Rd., Suite 201, Broadview Heights, OH 44147 for its method, metallic reduction, glucose (unvalidated non-quantitative) test system in a reagent tablet format classified under 21 CFR 862.1340.

IV. Reference

The following reference is on display in the Division of Dockets Management (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at http://www.regulations.gov. FDA has verified the Web site address, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.


Dated: March 17, 2016.

Leslie Kux,
Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0961]

Agency Information Collection Activities; Proposed Collection; Submission for Office of Management and Budget Review; Comment Request; Environmental Impact Considerations

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 (the PRA).

DATES: Fax written comments on the collection of information by April 25, 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 0910–0322. Also include the FDA docket number found in brackets in the heading of this document.