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.

GLUCOPHAGE (metformin hydrochloride) oral tablets, 500 mg, 850 mg, and 1 g, are the subject of NDA 020357, held by EMD Serono Inc. and initially approved on March 3, 1995. GLUCOPHAGE is indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus. GLUCOPHAGE (metformin hydrochloride) oral tablets, 500 mg, 850 mg, and 1 g, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

GLUCOPHAGE XR (metformin hydrochloride) oral extended-release tablets, 500 mg and 750 mg, are the subject of NDA 021202, held by EMD Serono Inc. and initially approved on October 13, 2000. GLUCOPHAGE XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. GLUCOPHAGE XR (metformin hydrochloride) oral extended-release tablets, 500 mg and 750 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Harman Finochem Ltd. submitted a citizen petition dated August 17, 2019 (Docket No. FDA–2019–P–3877), under 21 CFR 10.30, requesting that FDA confirm that GLUCOPHAGE (metformin hydrochloride) oral tablets were not withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the GLUCOPHAGE XR (metformin hydrochloride) oral extended-release tablets, 500 mg and 750 mg, those products have also been discontinued. On our own initiative, we have also determined whether those products were withdrawn for safety or effectiveness reasons.

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 GLUCOPHAGE (metformin hydrochloride) oral tablets, 500 mg, 850 mg, and 1 g, and GLUCOPHAGE XR (metformin hydrochloride) oral extended-release tablets, 500 mg and 750 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that GLUCOPHAGE (metformin hydrochloride) oral tablets were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of GLUCOPHAGE (metformin hydrochloride) oral tablets, 500 mg, 850 mg, and 1 g, and GLUCOPHAGE XR (metformin hydrochloride) oral extended-release tablets, 500 mg and 750 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 GLUCOPHAGE (metformin hydrochloride) oral tablets, 500 mg, 850 mg, and 1 g, and GLUCOPHAGE XR (metformin hydrochloride) oral extended-release tablets, 500 mg and 750 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to these drug products. Additional ANDAs for these drug products may also 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: December 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–28270 Filed 12–30–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–N–0134; FDA–2011–N–0902; FDA–2013–N–0662; FDA–2013–N–0242; FDA–2019–N–1517; FDA–2019–N–0549; FDA–2019–N–0305; FDA–2012–N–0477; FDA–2016–D–2565, and FDA–2018–N–4839]

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
Mammography Quality Standards Act Requirements	0910–0309	10/31/2022
Prescription Drug Product Labeling; Medication Guide Requirements	0910–0393	10/31/2022
Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed	0910–0513	10/31/2022
Current Good Manufacturing Practice for Positron Emission	0910–0667	10/31/2022

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB—Continued

Title of collection	OMB control No.	Date approval expires
Abbreviated New Animal Drug Applications	0910–0669	10/31/2022
Medical Devices: Use of Certain Symbols in Labeling—Glossary to Support the Use of Symbols in Labeling	0910–0740	10/31/2022
Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act	0910–0768	10/31/2022
Investigational Device Exemptions Reports and Records	0910–0078	11/30/2022
510(k) Third-Party Review Program	0910–0375	11/30/2022
Guidance for Industry With the Center for Veterinary Medicine's Electronic Submission System	0910–0454	11/30/2022

Dated: December 16, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–28249 Filed 12–30–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4319]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Unique Device Identification System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 January 30, 2020.

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 0910–0720. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Unique Device Identification System—21 CFR Parts 16, 801, 803, 806, 810, 814, 820, 821, 822, and 830

OMB Control Number 0910–0720—Extension

In accordance with the Unique Device Identification (UDI) system (see 21 CFR part 801, subpart B), medical device labelers, unless excepted, are required to design and use medical device labels and device packages that bear a UDI, present dates on labels in a particular format, and submit data concerning each version or model of a device to the Global Unique Device Identification Database (GUDID) no later than the date the label of the device must bear a UDI. Once a device becomes subject to UDI requirements, respondents will be required to update the information reported whenever the information changes.

The recordkeeping, reporting, and third-party disclosure requirements referenced in this document are imposed on any person who causes a label to be applied to a device, or who causes the label to be modified, with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label. In most instances, the labeler would be the device manufacturer, but other types of labelers include a specification developer, a single-use device reprocessor, a convenience kit assembler, a private label distributor, a repackager, or a relabeler. Respondents may also include any private organization that applies for accreditation by FDA as an issuing agency.

FDA has identified the following requirements as having burdens that must be accounted for under the PRA; the burdens associated with these requirements are summarized in the table that follows:

Section 801.18 requires that whenever a labeler of a medical device includes an expiration date, a date of manufacture, or any other date intended to be brought to the attention of the user of the device, the labeler must present the date on the label in a format that meets the requirements of this section.

Section 801.20 requires every medical device label and package to bear a UDI.

Under § 801.35, any labeler of a device that is not required to bear a UDI on its label may include a UDI on the label of that device and utilize the GUDID.

Under § 801.45, any device that has to be labeled with a UDI also has to bear a permanent marking providing the UDI on the device itself if the device is intended for more than one use and intended to be reprocessed before each use.

Section 801.50 requires stand-alone software to comply with specific labeling requirements that identify the software.

Section 801.55 authorizes additional, case-by-case, labeling exceptions and alternatives to standard UDI labeling requirements.

If a labeler relabels or modifies a label of a device that is required to bear a UDI, under § 830.60 it has to keep a record showing the relationship of the original device identifier to the new device identifier.

Section 830.110 requires an applicant seeking initial FDA accreditation as a UDI-issuing to furnish FDA an application containing certain information, materials, and supporting documentation.

Under § 830.120, an FDA-accredited issuing is required to disclose information concerning its system for the assignment of UDIs; maintain a list of labelers that use its system for the assignment of UDIs and provide FDA a copy of such list; and upon request, provide FDA with information concerning a labeler that is employing the issuing agency's system for assignment of UDIs.

Sections 830.310 and 830.320 require the labeler to provide certain information to the GUDID concerning the labeler and each version or model of a device required to be labeled with a UDI, unless the labeler obtains a waiver.