of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product OSENI (alogliptin benzoate and pioglitazone hydrochloride). OSENI is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Subsequent to this approval, the USPTO received a patent term restoration application for OSENI (U.S. Patent No. 6,329,404) from Takeda Pharmaceutical Company Limited, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 2, 2014, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of OSENI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for OSENI is 2,482 days. Of this time, 895 days occurred during the testing phase of the regulatory review period, while 1,587 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* April 12, 2006. The applicant claims April 13, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 12, 2006, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* September 22, 2008. FDA has verified the applicant's claim that the new drug application (NDA) for OSENI (NDA 22–426) was submitted on September 22, 2008.

3. *The date the application was approved:* January 25, 2013. FDA has verified the applicant's claim that NDA 22–426 was approved on January 25, 2013.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 6, 2015. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 3, 2015. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610.

Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11002 Filed 5–6–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0110]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Reporting: Manufacturer, Importer, User Facility, and Distributor Reporting

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 medical device reporting (MDR); manufacturer, importer, user facility, and distributor reporting.

DATES: Submit either electronic or written comments on the collection of information by July 6, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use

of automated collection techniques, when appropriate, and other forms of information technology.

Medical Device Reporting: Manufacturer, Importer, User Facility, and Distributor Reporting (21 CFR part 803) OMB Control Number 0910–0437—Extension

Section 519(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i(a)(1)) requires every manufacturer or importer to report whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury or has malfunctioned and that such device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Section 519(b)(1)(A) of the FD&C Act requires whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the death or serious illness, of a patient of the facility, the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the Secretary of HHS and, if the identity of the manufacturer is known, to the manufacturer of the device.

Section 519(b)(1)(B) of the FD&C Act requires whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the serious illness of, or serious injury to, a patient of the facility, shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the manufacturer of the device or to the Secretary of HHS if the identity of the manufacturer is not known.

Complete, accurate, and timely adverse event information is necessary for the identification of emerging device problems. Information from these reports will be used to evaluate risks associated with medical devices which will enable FDA to take appropriate regulatory measures in protection of the public health under section 519 of the FD&C Act. Thus FDA is requesting approval for these information collection requirements which are being implemented under part 803.

Respondents to this collection of information are businesses or other for-profit and nonprofit organizations including user facilities, manufacturers, and importers of medical devices.

Part 803 requires user facilities to report to the device manufacturer and to FDA in case of a death, incidents where a medical device caused or contributed to a death or serious injury. Additionally, user facilities are required to annually submit the number and summary of advents reported during the calendar year using Form FDA 3419. Manufacturers of medical devices are required to report to FDA when they become aware of information indicating that one of their devices may have caused or contributed to death or serious injury or has malfunctioned in such a way, that should the malfunction recur, it would be likely to cause or contribute to a death or serious injury. Device importers report deaths and serious injuries to the manufacturers and FDA. Importers report malfunctions only to the manufacturers, unless they are unknown, then the reports are sent to FDA.

The number of respondents for each CFR section in table 1 is based upon the number of respondents entered into FDA's internal databases. FDA estimates, based on its experience and interaction with the medical device community, that all reporting CFR sections are expected to take 1 hour to complete, with the exception of § 803.19. Section 803.19 is expected to take approximately 3 hours to complete, but is only required for reporting the summarized data quarterly to FDA. By summarizing events, the total time used to report for this section is reduced because the respondents do not submit a full report for each event they report in a quarterly summary report.

The Agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information to meet the MDR requirements as part of their internal quality control system. There are an estimated 30,000 medical device distributors. Although they do not submit MDR reports, they must maintain records of complaints under § 803.18(d).

The Agency has estimated that on average 220 user facilities, importers, and manufacturers would annually be required to establish new procedures, or revise existing procedures, in order to comply with this provision.

Therefore, FDA estimates the one-time burden to respondents for establishing or revising procedures under § 803.17 to be 2,200 hours (220 respondents × 10 hours). For those entities, a one-time burden of 10 hours is estimated for establishing written MDR procedures. The remaining manufacturers, user facilities, and importers, not required to revise their written procedures to comply with this provision, are excluded from the burden because the recordkeeping activities needed to comply with this provision are considered ''usual and customary'' under 5 CFR 1320.3(b)(2).

Under § 803.18, 30,000 respondents represent distributors, importers, and other respondents to this information collection. FDA estimates that it should take them approximately 1.5 hours to complete the recordkeeping requirement for this section. Total hours for this section equal 45,000 hours.

Reporting Requirements

Part 803 requires user facilities to report incidents where a medical device caused or contributed a death or serious injury to the device manufacturer and to FDA in the case of a death. Manufacturers of medical devices are required to report to FDA when they become aware of information indicating that one of their devices may have caused or contributed to death or serious injury or has malfunctioned in such a way that, should the malfunction recur, it would be likely to cause or contribute to a death or serious injury. Device importers report deaths and serious injuries to the manufacturers and FDA. Importers report malfunctions only to the manufacturers (see third-party disclosure burden table), unless the manufacturers are unknown, then the reports are sent to FDA.

FDA estimates, based on its experience and interaction with the medical device community, that all reporting CFR sections are expected to take 1 hour to complete with the exception of § 803.19. Section 803.19 is expected to take approximately 3 hours to complete, but is only required to report the summarized data quarterly to FDA. By summarizing events, the total time used to report for this section is reduced because the respondents do not submit a full report for each event they report in a quarterly summary report.

Recordkeeping Requirements

The Agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information to meet the MDR requirements as part of their internal quality control system. There are an estimated 30,000 medical device distributors. Although they do not submit MDR reports, they must maintain records of complaints under § 803.18(d). We estimate that it will take

each respondent 1.5 hours annually to maintain the records.

The Agency has estimated that on average, 220 user facilities, importers, and manufacturers would annually be required, under § 803.17, to establish new procedures, or revise existing procedures, in order to comply with this provision. We estimate that it will take each respondent 10 hours annually to establish new procedures, or revise existing procedures.

Third-Party Disclosure Burden

Under §§ 803.40 and 803.42, device importers report deaths and serious injuries to the manufacturers and FDA. Importers report malfunctions only to the manufacturers, unless they are unknown, then the reports are sent to FDA. We estimate that it will take respondents 1 hour annually to report the information.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Exemptions—803.19		57	4	228	3	684
User Facility Reporting—803.30 and 803.32		544	9	4,896	1	4,896
User Facility Annual Reporting—803.33	3419	195	1	195	1	195
Importer Reporting, Death and Serious Injury—803.40 and 803.42		1	1	1	1	1
Manufacturer Reporting—803.50, through 803.53		1,239	243	301,077	1	301,077
Supplemental Reports—803.56		124	302	37,448	1	37,448
Total						344,301

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record	Total hours
MDR Procedures—803.17	220	1	220	10	2,200
MDR Files—803.18	30,000	1	30,000	1.5	45,000
Total					47,200

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Importer Reporting, Malfunctions—803.40 and 803.42	1	25	25	1	25

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

Dated: May 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–10995 Filed 5–6–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Joint Meeting of the Bone, Reproductive, and Urologic Drugs Advisory Committee, and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of two public advisory committees of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Bone, Reproductive, and Urologic Drugs Advisory Committee, and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 4, 2015, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions