addition to data collection for the certification of QHPs, the reinsurance and risk adjustment programs outlined by the Affordable Care Act, detailed in 45 CFR part 153, as established by CMS–9975–F, Patient Protection and Affordable Care Act; Standards for Reinsurance, Risk Corridors, and Risk Adjustment (77 FR 17220), published in March 23, 2012, have general information reporting requirements that apply to issuers, group health plans, third party administrators, and plan offerings outside of the Exchanges. Subsequent regulations for these programs including the final HHS Notice of Benefit and Payment Parameters for 2014 and the Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 provide further reporting requirements. *Form Number:* CMS–10433 (OMB Control Number 0938–1187); *Frequency:* Annually; *Affected Public:* States and Private Sector; *Number of Respondents:* 26,951; *Number of Responses:* 26,951; *Total Annual Hours:* 235,153. (For questions regarding this collection contact Leigha Basini at 301–492–4380.)

Dated: November 12, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–29343 Filed 11–17–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2015–M–1707, FDA–2015–M–2218, FDA–2015–M–2217, FDA–2015–M–2497, FDA–2015–M–2219, FDA–2015–M–2499, FDA–2015–M–2634, FDA–2015–M–2584, FDA–2015–M–2618, FDA–2015–M–2739, FDA–2015–M–2740, and FDA–2015–M–2964]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. 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 Nos. FDA–2015–M–1707, FDA–2015–M–2218, FDA–2015–M–2217, FDA–2015–M–2497, FDA–2015–M–2219, FDA–2015–M–2499, FDA–2015–M–2634, FDA–2015–M–2584, FDA–2015–M–2618, FDA–2015–M–2739, FDA–2015–M–2740, and FDA–2015–M–2964 for ''Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications.'' 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 dockets, 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: Melissa Torres, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–5576.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will

continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from July 1, 2015, through September 30, 2015. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JULY 1, 2015, THROUGH SEPTEMBER 30, 2015

PMA No., docket No.	Applicant	Trade name	Approval date
P930016/S044, FDA–2015–M–1707	AMO Manufacturing USA, LLC	STAR S4 IR Exciter Laser System and iDesign WaveScan Studio System.	5/6/2015
P120024, FDA–2015–M–2218	Aesculap Implant Systems, LLC	activL® Artificial Disc	6/11/2015
P140021, FDA–2015–M–2217	Roche Diagnostics Operations, Inc	Elecsys® Anti-HCV II Immunoassay and Elecsys® PreciControl Anti-HCV.	6/11/2015
P140009, FDA–2015–M–2497	St. Jude Medical Neuromodulation	Brio Neurostimulation System	6/12/2015
P140025, FDA–2015–M–2219	Ventana Medical Systems, Inc	VENTANA ALK (D5F3) CDx Assay	6/12/2015
P140031, FDA–2015–M–2499	Edwards Lifesciences, LLC	SAPIEN 3™ Transcatheter Heart Valve and Accessories.	6/17/2015
P040024/S073, FDA–2015–M–2634	Galderma Laboratories L.P.	Restylane Lyft with Lidocaine	7/1/2015
H080004, FDA–2015–M–2584	Integrum AB	Osseoanchored Prostheses for the Rehabilitation of Amputees (OPRA).	7/16/2015
P140028, FDA–2015–M–2618	Boston Scientific Corporation	Innova™ Vascular Self-Expanding Stent System.	7/21/2015
P140013, FDA–2015–M–2739	Minerva Surgical, Inc	Minerva™ Endometrial Ablation System.	7/27/2015
P140012, FDA–2015–M–2740	ReShape Medical, Inc	ReShape Integrated Dual Balloon System.	7/28/2015
P140008, FDA–2015–M–2964	Apollo Endosurgery, Inc	ORBERA™ Intragastric Balloon System.	8/5/2015

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm.*

Dated: November 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29450 Filed 11–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0530]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Tropical Disease Priority Review Vouchers

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 December 18, 2015.

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-New and title ''Guidance for Industry on Tropical Disease Priority Review Vouchers.'' 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Guidance for Industry on Tropical Disease Priority Review Vouchers—OMB Control Number 0910–NEW

Section 1102 of the Food and Drug Administration Amendments Act (FDAAA) adds new section 524 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360n). Section 524 is designed to encourage development of new drug or biological products for prevention and treatment of certain tropical diseases affecting millions of people throughout the world and makes provisions for awarding priority review vouchers for future applications to sponsors of tropical disease products. By enacting section 524, Congress intended to stimulate new drug development for drugs to treat certain tropical diseases for which there are no or few available treatments by offering additional incentives for obtaining FDA approval for pharmaceutical treatments for these diseases. Under section 524, a sponsor of a human drug application for a