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

qualified tropical disease may be eligible for a voucher that can be used to obtain a priority review for any application submitted under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351 of the Public Health Service Act (the PHS Act). The guidance explains to internal and external stakeholders how FDA intends to implement the provisions of section 524, and provides information on using the priority review vouchers and on transferring priority review vouchers to other sponsors.

Under the guidance, sponsors of certain tropical disease drug product applications submitted under section 505(b)(1) of the FD&C Act and section 351 of the PHS Act may request a priority review voucher. Based on inquiries and discussions with industry about section 524, we estimate that we will receive annually approximately five requests from five sponsors, and that each request will take approximately 8 hours to prepare and submit to FDA.

The guidance also states that sponsors should notify FDA of their intent to use a priority review voucher, including the date on which the sponsor intends to submit the application, at least 90 days before use. We estimate that we will receive annually approximately five notifications of intent to use a voucher from five sponsors, and that each notification will take approximately 8 hours to prepare and submit to FDA.

The guidance also permits the transfer of a priority review voucher from one sponsor to another, and states that each transfer should be documented with a letter of transfer. We estimate that we will receive approximately two letters indicating the transfer of a voucher from two application holders, and two letters from two new voucher owners acknowledging the transfer, and that it will take approximately 8 hours to prepare and submit each letter to FDA.

In the **Federal Register** of October 20, 2008 (73 FR 62298), FDA published a 60-day notice requesting public comment on the proposed collection of information. The comments we received did not pertain to the information collection that would result from the guidance (that is, the four types of submissions estimated in table 1).

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

*Description of Respondents:* Sponsors submitting applications under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Guidance for Industry on Tropical Disease Priority Review Vouchers | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Priority Review Voucher Request | 5 | 1 | 5 | 8 | 40 |
| Notifications of Intent To Use a Voucher | 5 | 1 | 5 | 8 | 40 |
| Letters Indicating the Transfer of a Voucher Letter | 2 | 1 | 2 | 8 | 16 |
| Acknowledging the Receipt of a Transferred Voucher | 2 | 1 | 2 | 8 | 16 |
| Total | | | | | 112 |

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

Dated: November 12, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–29406 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–2013–D–0286]**

### Formal Meetings Between the Food and Drug Administration and Biosimilar Biological Product Sponsors or Applicants; Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants.'' This guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The guidance assists sponsors and applicants in generating and submitting meeting requests and the associated meeting packages to FDA for biosimilar biological products. This guidance finalizes the draft guidance issued on April 1, 2013.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**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,