ANNUAL BURDEN ESTIMATES—Continued

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Electronic Data Reporting: Services Measures	19	2	8	912	304
Outcomes Data Tables in End of Year Reports	27	1	8	648	216

Estimated Total Annual Burden Hours: 844.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Steven M. Hanmer,

Reports Clearance Officer.

[FR Doc. 2013–03787 Filed 2–21–13; 8:45 am]

BILLING CODE 4184–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0114]

Distinguishing Medical Device Recalls From Product Enhancements; Reporting Requirements; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Distinguishing Medical Device Recalls From Product Enhancements; Reporting Requirements.'' This draft guidance intends to clarify for industry when a potential change to a device is a medical device recall, distinguish those instances from product enhancements, and identify the reporting requirements for both recalls and product enhancements. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 23, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Distinguishing Medical Device Recalls From Product Enhancements; Reporting Requirements'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ron Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2654, Silver Spring, MD 20993–0002, 301–796–6163.

I. Background

Defects or performance failures of marketed medical devices can pose serious risks to public health. Recalls serve both to correct the defect in current and future devices and to notify users of potential risks and steps to minimize the impact of device failure or function. The recall process establishes a mechanism for firms that produce and market medical devices to take timely action to correct violative devices or remove them from the marketplace when correction or removal is necessary to protect the public health.

When a firm's recall process is operating effectively, the firm identifies a device defect or failure, determines a recall is appropriate, and triggers the initiation of the recall process. However, firms may have trouble identifying whether a change to a device meets the definition of a recall, the appropriate scope of a recall, and when FDA should be notified of a recall. These issues can result in delays in notifying the public about unsafe medical devices.

FDA also recognizes that continuous improvement activities, as part of an effective quality system, often have a favorable impact on medical device safety and are part of ongoing efforts to design and manufacture devices that meet the needs of the user and patient. When new iterations of a device involve improvements to device design, it does not necessarily mean that the existing device needs to be recalled. Such changes may be appropriately characterized instead as product enhancements.

In addition to determining whether a proposed change to a marketed device meets the definition of a device recall or

a product enhancement, a firm must make a separate assessment on whether it is required to report the change to FDA.

The guidance is organized in a question-and-answer format, providing responses to questions that FDA believes are helpful in properly identifying medical device recalls and applying the reporting requirements.

II. Significance of Guidance

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the difference between a recall and an enhancement to an existing premarket approval application (PMA) or 510(k). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* To receive ''Distinguishing Medical Device Recalls From Product Enhancements; Reporting Requirements,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1819 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 7, subpart C have been approved under OMB control number 0910–0249; the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; and the collections of information in 21 CFR part 810 have been approved under OMB control number 0910–0432.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: February 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04060 Filed 2–21–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–E–0196]

Determination of Regulatory Review Period for Purposes of Patent Extension; SAPIEN TRANSCATHETER HEART VALVE

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SAPIEN TRANSCATHETER HEART VALVE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6284, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device, SAPIEN TRANSCATHETER HEART VALVE. SAPIEN TRANSCATHETER HEART VALVE is indicated for transfemoral delivery in patients with severe symptomatic native aortic valve stenosis who have been determined by a cardiac surgeon to be inoperable for open aortic valve replacement and in whom existing comorbidities would not preclude the expected benefit from correction of the aortic stenosis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SAPIEN TRANSCATHETER HEART VALVE (U.S. Patent No. 5,411,552) from Edwards Lifesciences AG and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 10, 2012, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of SAPIEN TRANSCATHETER HEART VALVE represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that the