4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0842]

Division of Cardiovascular Devices 30-Day Notices and Annual Reports; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled "Division of Cardiovascular Devices 30-Day Notices and Annual Reports." This public workshop will be cosponsored with Advanced Medical Technology Association (AdvaMed). The purpose of this public workshop is to discuss details of, and issues relating to, two types of reporting requirements applicable to premarket approval applications (PMAs), 30-day notices and annual reports, specifically for cardiovascular devices.

Date and Time: The public workshop will be held on August 28, 2012, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to:

http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

Contact: Lindsay K. Pack, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1260, Silver Spring, MD 20993, 301-796-5214, email: Lindsay.pack@fda.hhs.gov.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 5 p.m., August 17, 2012. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Joyce Raines, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4319, Silver Spring, MD 20993, 301-796-5709, email: joyce.raines@fda.hhs.gov.

To register for the public workshop, please visit FDA's Medical Devices News & Events--Workshops & Conferences calendar at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Lindsay Pack to register (see Contact). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. Persons interested in viewing the webcast must register online by 5 p.m., August 17, 2012. Early registration is recommended because webcast connections are limited. Organizations are

requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after August 22, 2012. If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Comments: FDA is holding this public workshop to discuss issues related to 30-day notices and annual reporting requirements as they pertain to manufacturing changes to class III cardiovascular devices that are the subject of a PMA. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is September 26, 2012.

Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments. Submit electronic comments 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. It is only necessary to send one set of comments. Please 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.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list.)

SUPPLEMENTARY INFORMATION:

I. Background

Under section 515(d)(6)(A) of the Federal Food, Drug, and Cosmetic Act (section 360e(d)(6)(A) of the FD&C Act) and 21 CFR 814.39(a), PMA supplements are required for any change to a device subject to an approved application that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing. Under the FD&C Act and 21 CFR 814.39(f), changes in manufacturing procedures or methods of manufacture that affect the safety or effectiveness of the device require a 30-day notice (however, if FDA finds that the notice is inadequate, a supplement will be required). Additionally, under 21 CFR 814.39(b), a manufacturer may make a change to a device after FDA's approval of a PMA for the device without submitting a PMA supplement if the change does not affect the safety or effectiveness of the device and the change is reported to FDA in a post approval periodic (annual) report.

This workshop is intended to focus on manufacturing method and procedure changes to Class III cardiovascular devices, which could be submitted to FDA in a 30-day notice or annual report, depending on the change. A guidance document issued on April 13, 2011, entitled "30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes" outlines FDA's current thinking on which changes may qualify for a 30-day notice and which changes may require other submission types (supplements, annual reports, etc.). This workshop will allow a deeper discussion of relevant considerations when determining the appropriate submission for manufacturing changes to Class III cardiovascular devices.

II. Topics for Discussion at the Public Workshop

FDA is holding this public workshop to discuss a variety of issues relating to two types of reporting requirements applicable to PMAs, 30-day notices and annual reports, specifically for cardiovascular devices. These issues include, but are not limited to:

- Considerations that go into determining if a change is appropriate for an annual report or 30-day notice (e.g., equipment changes, software changes, supplier changes);
- Best practices for submission contents;
- Other issues and questions raised by the public workshop attendees that are relevant to 30-day notices and annual reports for cardiovascular devices.

Dated: August 7, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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