

Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002; or Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. 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Submit electronic comments on the draft guidance to 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:
Geeta Pamidimukkala, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1564, Silver Spring, MD 20993-0002, 301-796-6453; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6210.

I. Background

The purpose of the 510(k) acceptance review is to make a threshold determination whether a submission is administratively complete, which determines whether it should be accepted for substantive review to reach a determination regarding substantial equivalence under section 513(i) of the FD&C Act, 21 U.S.C. 360c(i). To find a device substantially equivalent under section 513(i) of the FD&C Act, FDA must find that it has the same intended use as the predicate device, and either: (1) Has the same technological characteristics as the predicate device or (2) has different technological characteristics, as defined at section 513(i)(1)(B), and the submission contains information, including appropriate clinical or scientific data if necessary, that demonstrates the device is as safe and effective as the predicate and does not raise different questions of safety and effectiveness than the predicate.

The purpose of this document is to explain the procedures and criteria FDA intends to use in determining whether a 510(k) submission is administratively

complete and should be accepted for substantive review. This guidance document provides updated information to two existing guidance documents entitled "Center for Devices and Radiological Health's Premarket Notification (510(k)) Refuse to Accept Policy" issued on June 30, 1993, and "510(k) Refuse to Accept Procedures, 510(k) Memorandum K94-1" issued on May 20, 1994. Upon issuance as a final guidance document, this guidance will replace those documents.

To further focus the Agency's review resources on complete applications, which will provide a more efficient approach to ensuring that safe and effective medical devices reach patients as quickly as possible, we have modified the 1993 and 1994 guidances. For example, we have modified the 510(k) refuse to accept policy to include an early review against specific acceptance criteria and to inform the submitter within the first 15 calendar days of receipt of the submission if the submission is administratively complete, or if not, to identify the missing element(s). In order to enhance the consistency of our acceptance decisions and to help submitters better understand the types of information FDA needs to conduct a substantive review, this guidance, including the checklists included in the appendices, clarifies the necessary elements and contents of a complete 510(k) submission. These elements are applicable to all devices reviewed through the 510(k) notification process in CDRH and CBER and have been compiled into checklists for use by FDA review staff.

II. Significance of Guidance

This 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 refuse to accept policy for 510(k)s. 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.fda.gov/BiologicsBlood>

Vaccines/GuidanceComplianceRegulatoryInformation/default.htm or <http://www.regulations.gov>.

To receive "Refuse to Accept Policy for 510(k)s," 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 1793 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently 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 807, subpart E, have been approved under OMB control number 0910-0120.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. 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.

Dated: August 7, 2012.

Leslie Kux,
Assistant Commissioner for Policy.
[FR Doc. 2012-19744 Filed 8-10-12; 8:45 am]

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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.

DATES: 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Requirements and Registration for the Challenge To Identify Audacious Goals in Vision Research and Blindness Rehabilitation

Authority: 15 U.S.C. 3719.

SUMMARY: The National Eye Institute (NEI) is announcing the launch of the *Challenge to Identify Audacious Goals in Vision Research and Blindness Rehabilitation* (Challenge) to stimulate innovation in establishing a national vision research agenda. This Challenge seeks entries from the general public, not just those typically engaged in vision research. The challenge calls for submission of audacious goals in any area relevant to NEI's mission to conduct and support research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems and requirements of the blind (42 U.S.C. 285i).

The NEI will select up to 20 winners to receive a \$3,000 cash prize and will host the winners at the NEI Audacious Goals Development Meeting to present and discuss their winning entries with a broad audience of scientists, NEI staff, and other stakeholders. This challenge will generate valuable contributions from NEI's many and varied stakeholders to inform the Institute's strategic plan, energize the Institute's research efforts, increase public awareness of vision research, and enhance the national effort to reduce the burden of ocular disorders and diseases worldwide.

DATES:

- (1) Submission period begins August 13, 2012.
- (2) Submission period ends November 12, 2012, 6:00 p.m. ET.
- (3) Winners notified January 7, 2013.
- (4) Winners present and discuss their winning entry at the NEI Audacious Goals Development Meeting in early 2013 (date will be announced on <http://www.nei.nih.gov/challenge>).

FOR FURTHER INFORMATION CONTACT:

Richard S. Fisher, Ph.D., Associate Director for Science Policy and Legislation, National Eye Institute, Phone: 301-496-4308. [NEIPlan@mail.nih.gov]

SUPPLEMENTARY INFORMATION:

Subject of Challenge Competition

This *Challenge to Identify Audacious Goals in Vision Research and Blindness Rehabilitation* (Challenge) adds an exciting, unique component to the NEI's current strategic planning effort. In the past, these planning efforts relied primarily on the expertise of NEI-funded scientists to review the state of the science and describe current specific research needs and opportunities. This Challenge seeks input from all eligible individuals (Contestants)—not just vision research scientists—to describe (a) an audacious goal in vision research and blindness rehabilitation, (b) how to achieve the goal within about 10 years, and (c) the impact of reaching the goal.

Rules for Participating in the Competition

1. Eligibility: To be eligible to win a prize under this Challenge, a Contestant:

- Shall have registered to participate in the competition under the rules promulgated by the NEI and explained in this Notice;
- Shall have complied with all the requirements under this section;
- Shall be an individual at least 18 years of age and shall be a citizen or permanent resident of the United States;
- May not be a Federal entity or Federal employee acting within the scope of their employment. Federal employees seeking to participate in this contest outside the scope of their employment should consult their ethics official prior to developing their submission;
- May not be employees of the NIH or any other company or individual involved with the design, production, execution, judging, or distribution of the Challenge and their immediate family (spouse, parents and step-parents, siblings and step-siblings, and children and step-children) and household members (people who share the same

residence at least three (3) months out of the year);

2. Federal grantees may not use Federal funds to develop America COMPETES Act Challenge applications unless consistent with the purpose of their grant award (Grantees should consult with their cognizant Grants Management Official to make this determination); and

3. Federal contractors may not use Federal funds from a contract to develop a Challenge entry or to fund efforts in support of a Challenge submission.

4. A Contestant shall not be deemed ineligible because the individual used Federal facilities or consulted with Federal employees during a competition if the facilities and employees are made available to all individuals participating in the competition on an equitable basis.

5. **Liability:** By participating in this Challenge, Contestants agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from participation in this prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise.

6. **Indemnification:** By participating in this Challenge, Contestants agree to indemnify the Federal Government against third party claims for damages arising from or related to competition activities.

7. **Insurance:** Based on the subject matter of the contest, the type of work that it will possibly require, as well as an analysis of the likelihood of any claims for death, bodily injury, or property damage, or loss potentially resulting from contest participation, Contestants are not required to obtain liability insurance or demonstrate financial responsibility in order to participate in this contest.

8. By participating in this Challenge, each individual agrees to abide by all rules set forth in this Notice and the Challenge.gov Terms of Participation (<http://challenge.gov/terms>).

9. **Each Entry Must:**

- Be limited to a maximum of 4,000 characters, including spaces (roughly a single page). In addition to information requested by <http://www.nei.nih.gov/challenge> to identify the entry, Contestants must complete three statements about the proposed audacious goal. The following statements, which will be the subject of the judging, are:

■ It would be fantastic if * * * (Explain why the goal is audacious and