4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0057]

Cardiovascular Metallic Implants: Corrosion, Surface Characterization, and Nickel Leaching; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Cardiovascular Metallic Implants: Corrosion, Surface Characterization, and Nickel Leaching." The purpose of this public workshop is to provide a forum for FDA, cardiovascular device manufacturers, test houses, and academia to discuss corrosion, surface characterization, and nickel leach testing, as well as to collect comments and input regarding when these assessments should be considered.

Dates and Time: The public workshop will be held on March 8 and 9, 2012, from 9 a.m. to 5:30 p.m. EST.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503 (the Great Room), Silver Spring, MD, 20993. For parking and security information, please visit the following Web site: http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm. The public workshop will also be available to be viewed online via webcast.

Contact Persons:

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Registration: To register for the public workshop, please visit the following Web site: http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm (or go to http://www.fda.gov and select the FDA Medical Devices News & Events--Workshops & Conferences calendar and 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. For those without Internet access, please call the Contact Person to register. Registration is mandatory as space is limited and onsite registration will not

be available. FDA may limit the number of participants from each organization. There is no registration fee for the public workshop. Registration requests should be received by 5 p.m. E.S.T. on February 21, 2012.

If you need special accommodations due to a disability, please contact Susan Monahan, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4321, Silver Spring, MD, 20993, 301-796-5661 or email: susan.monahan@fda.hhs.gov at least 7 days in advance of the workshop.

Streaming Webcast of the Public Workshop: This workshop will also be webcast. Persons interested in viewing the webcast must register online by 5 p.m. E.S.T. on February 21, 2012. Early registration is recommended because webcast connections are limited. Organizations are requested to register all participants, but view using one connection per location. Webcast participants will be sent technical system requirements after registration, and will be sent connection access information in a final confirmation email by 5 p.m. E.S.T. on March 2, 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).

Workshop Participation: Participation in the workshop will consist of both lead participants and audience members. Lead participants will include representatives from various organizations involved in or who perform corrosion testing, surface characterization, and/or nickel leach testing and toxicological assessments of nickel, such as industry, the medical community, and test houses, and will be driving the discussions. Lead participants are expected

to complete a work assignment in advance of the workshop in order to optimize the time spent during the workshop. FDA will compile the work assignment responses prior to the workshop so that any information provided from the responding organization is de-identified.

If you wish to participate as a lead participant, you must indicate this at the time of registration. There will be a tentative limit of one lead participant per organization for industry and two for test houses for each session, with a total workshop participation limit of two industry participants and three for test houses, due to space limitations. Audience members may be able to participate in discussions, if time permits.

Additional Information: Background information on the public workshop, registration information, agenda, information about lodging, food services, and other relevant information will be posted, as it becomes available, on the Internet at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm (or go to http://www.fda.gov and select the FDA Medical Devices News & Events--Workshops and Conferences calendar and select this public workshop from the posted events list).

Comments: FDA is holding this public workshop to obtain information on a number of questions regarding corrosion, surface characterization, and nickel leaching. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting written or electronic comments on all aspects of the workshop topics. The deadline for submitting comments related to this public workshop is April 6, 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. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific topics as outlined in section II of this document, please identify the topic you are addressing. 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.

SUPPLEMENTARY INFORMATION

I. Background and Objectives

While the majority of cardiovascular implants are made of metals and may be susceptible to corrosion, it is unclear whether the current corrosion testing paradigm is predictive of in vivo corrosion outcomes, or if there may be more suitable assessments to predict corrosion failure. In addition, there has been an increase in the use of nitinol, a nickel-titanium alloy, in cardiovascular implants due to its superelastic properties, which are ideal for transcatheter-delivered therapies. Corrosion of implant devices made of nitinol and other nickel-containing metal alloys (e.g. stainless steel, MP35N) results in the release of nickel ions, which may lead to various modes of toxicities. Furthermore, both nickel ion release and corrosion characteristics are dependent on surface finishing for nitinol as well as for some other nickel-containing alloys. Through the collection of information from a pre-workshop work assignment and discussions with workshop participants, FDA will be able to better determine what assessments may be considered for cardiovascular implants made of commonly used metallic alloys, and this information is expected to serve as the foundation for a future guidance document.

II. Topics for Discussion at the Public Workshop

The objective of this workshop is to provide a forum for discussion of the following topics:

- The various methods that are used for corrosion assessments, surface characterization techniques, and nickel leach testing used to evaluate the suitability of metallic cardiovascular implant devices;
- The limitations of each of these tests to predict actual in vivo performance;
- The need and utility for each test; and
- The potential testing paradigms, including when certain tests should be considered, and how to establish acceptance criteria for each test.

III. 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 (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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 on the Internet at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm (select this public workshop from the posted events list), approximately 45 days after the public workshop.

Dated: February 1, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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