4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0920]

Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems; 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 guidance entitled "Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems." FDA has developed this guidance to inform the coronary and peripheral stent industry about selected updates to FDA's thinking regarding certain non-clinical testing for these devices. While FDA is considering more substantial updates to the "Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems" guidance (http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm071863.htm), we are issuing this update on select sections in order to notify the industry in a timely manner of our revised recommendations.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the 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: Katharine Chowdhury, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1222, Silver Spring, MD 20993-0002, 301-796-6344, or Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, rm. 3226, Silver Spring, MD 20993-0002, 301-796-6353.

SUPPLEMENTARY INFORMATION:

I. Background

FDA held a public workshop entitled "Cardiovascular Metallic Implants: Corrosion, Surface Characterization, and Nickel Leaching" on March 8 and 9, 2012, that provided information on current practices for performing these tests (see http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm287535.htm). A

group of participants from industry, test facilities, and academia provided comments on practices for corrosion testing and nickel ion release testing. Based on the discussion at the workshop, this guidance updates a key aspect of sample conditioning for pitting corrosion testing that is less burdensome, and includes additional information on when galvanic corrosion testing may be omitted with justification, based on information gained from the workshop. This guidance provides updates only for the following topics:

- Pitting corrosion potential
- Galvanic corrosion
- Surface characterization
- Nickel ion release

This guidance provides cross-references and updates to the related sections of the existing "Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems" guidance.

In the Federal Register on August 30, 2013 (78 FR 53773), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by September 30, 2013. Four sets of comments were received and, in general, were supportive of the guidance. There were multiple comments regarding the need for clarification of acceptance criteria and the desire for a flow chart to visualize the overall testing paradigm described in the guidance update. In response to these comments, FDA revised the guidance document to include more specific information on acceptance criteria for pitting corrosion and surface oxide properties, as well as a flow chart. General concerns were noted that the guidance modifications might be interpreted to be more burdensome. However, the addition of the flowchart is intended to clarify when testing beyond pitting corrosion testing should be considered, and based on prior

experience, it is anticipated that few stents will need further assessment. In addition, there were several comments regarding the lack of utility of post-fatigue pitting corrosion assessment. In response to these comments, as well as discussions at the March 2012 workshop, FDA has removed the suggestion to consider post-fatigue pitting corrosion testing when damage to samples is noted due to fatigue testing. There was also a comment that the 60-day suggested duration for nickel release may be unnecessarily long and burdensome, and in response, FDA has reduced the minimum duration to 30 days if the release rate falls below a predetermined level based on toxicological risk assessment.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on certain non-clinical testing for coronary and peripheral stents. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. Persons unable to download an electronic copy of "Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems " may send an

email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1826 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This 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 814 have been approved under OMB control number 0910-0231.

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: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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