4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-1788]

Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings--Labeling Considerations; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings--Labeling Considerations." This draft guidance addresses labeling considerations for devices containing lubricious coatings that are used in the vasculature. The purpose of this draft guidance is to provide recommendations for information to be included in device labeling, as submitted in premarket applications (PMAs) or premarket notification submissions (510(k)s) for class III and class II devices, to enhance the consistency of information across these product areas as well as to promote the safe use of these devices in clinical settings. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-D-1788 for "Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings--Labeling Considerations." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the draft 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 draft guidance document entitled "Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings--Labeling Considerations" 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.

FOR FURTHER INFORMATION CONTACT: Leigh Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2656, Silver Spring, MD 20993-0002, 301-796-5613.

SUPPLEMENTARY INFORMATION:

I. Background

Hydrophilic- and/or hydrophobic-coated devices have been used for more than 20 years in minimally invasive diagnostic and therapeutic cerebrovascular, cardiovascular, and peripheral vascular procedures. Although these devices may offer patient benefits, evidence indicates that the coating may separate from intravascular devices in some circumstances. FDA has received

and analyzed information concerning serious adverse events associated with hydrophilic and/or hydrophobic coatings separating (e.g., peeling, flaking, shedding, delaminating, or sloughing off) from intravascular medical devices.

FDA has not concluded that any specific manufacturer or brand of these devices is associated with higher risks than others. The cause of coating separation is multifactorial, and can be associated with factors including device design, manufacturing, and use. Current FDA analysis suggests that use-related issues may be mitigated through proper device selection, preparation, and other labeling considerations that are addressed within this draft guidance.

This draft guidance addresses labeling considerations for devices containing lubricious coatings used in the vasculature. The purpose of this draft guidance is to provide recommendations for information to be included in device labeling, as submitted in PMAs or 510(k)s for class III and class II devices, to enhance the consistency of coating information across these product areas as well as to promote the safe use of these devices in clinical settings.

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 current thinking of FDA on "Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings--Labeling Considerations." 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 statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft 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 https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. This draft guidance document is also available at https://www.regulations.gov. Persons unable to download an electronic copy of "Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings--Labeling Considerations" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 16016 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 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subparts A through E have been approved under OMB control number 0910-0231; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.

Dated: June 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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