information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings—Labeling Considerations'' to the Office of Policy, 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, 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, device 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 guidance.

This guidance addresses labeling considerations for devices containing lubricious coatings used in the vasculature. The purpose of this guidance is to provide recommendations for information to be included in the device labeling, as submitted in PMAs or premarket notification submissions (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 the clinical setting.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of June 15, 2018 (83 FR 27996). FDA revised the guidance as appropriate in response to the comments.

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 labeling considerations for intravascular catheters, wires, and delivery systems with lubricious coating. 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 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 guidance 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 guidance refers to previously approved collections of information. 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. 3501–3521). The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
807, subpart E	Premarket Notification	0910–0120
814, subparts A through E	Premarket Approval	0910–0231
801	Medical Device Labeling Regulations	0910–0485

Dated: October 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22192 Filed 10–9–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1775]

Coronary, Peripheral, and Neurovascular Guidewires—Performance Tests and Recommended Labeling; 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 a final guidance entitled ''Coronary, Peripheral, and Neurovascular Guidewires—Performance Tests and Recommended Labeling.'' This guidance provides recommendations for the information and testing that should be included in premarket submissions for guidewires intended for use in the coronary vasculature, peripheral vasculature, and neurovasculature.

DATES: The announcement of the guidance is published in the **Federal Register** on October 10, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–1775 for ''Coronary, Peripheral, and Neurovascular Guidewires—Performance Tests and Recommended Labeling.'' 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 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 ''Coronary, Peripheral, and Neurovascular Guidewires—Performance Tests and Recommended Labeling'' to the Office of Policy, 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: Nicole Goodsell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2309, Silver Spring, MD 20993–0002, 240–402–6600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled ''Coronary, Peripheral, and Neurovascular Guidewires—Performance Tests and Recommended Labeling.'' This guidance updates and clarifies performance testing and labeling recommendations to support a premarket notification (510(k) submission) for guidewires intended for use in the coronary vasculature, peripheral vasculature, and neurovasculature. The recommendations reflect current review practices and are intended to promote consistency and facilitate efficient review of these submissions. This guidance is also intended to assist industry in designing and executing appropriate performance testing to support a premarket notification and provides recommendations for content and labeling to include in the submission. FDA considered comments received on the draft guidance that appeared in the **Federal Register** of June 15, 2018 (83 FR 27998). FDA revised the guidance as appropriate in response to the comments. This guidance supersedes ''Coronary and Cerebrovascular Guidewire Guidance,'' dated January 1995 (available at: *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080789.pdf*).

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 coronary, peripheral, and neurovascular guidewires performance tests and recommended labeling. 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 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 guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy

of ''Coronary, Peripheral, and Neurovascular Guidewires—Performance Tests and Recommended Labeling'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 16007 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. 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. 3501–3521). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
812	Investigational Device Exemption	0910–0078
''Requests for Feedback on Medical Device Submissions: The Q-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073

Dated: October 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22194 Filed 10–9–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4041]

Advancing the Development of Pediatric Therapeutics: Pediatric Clinical Trial Endpoints for Rare Diseases With a Focus on Pediatric Patient Perspectives; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Office of Pediatric Therapeutics, Food and Drug Administration (FDA), is announcing a public workshop entitled ''Advancing the Development of Pediatric Therapeutics (ADEPT 6): Pediatric Clinical Trial Endpoints for Rare Diseases with a Focus on Pediatric Patient Perspectives.'' The purpose of this workshop is to discuss pediatric patient-specific engagement in the development of clinical trial endpoints for rare diseases.

DATES: The public workshop will be held on November 12, 2019, from 8 a.m. to 4:30 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503–A), Silver Spring, MD 20993–0002. 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 *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Terrie L. Crescenzi, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8646, email: *terrie.crescenzi@fda.hhs.gov;* or Elizabeth Sanford, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8659, email: *elizabeth.sanford@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Patient engagement is critical in the development of patient-focused study endpoints that measure clinical benefit in clinical trials. Asking patients what aspects of their disease they consider important to measure is especially important for rare diseases, given the lack of established endpoints for many rare diseases, the small number of patients available for enrollment in trials, and the heterogeneity of disease manifestations (*e.g.,* between patients and over time). While there is increased emphasis on incorporating the patient voice in rare disease drug development activities, there is an increased need for pediatric patient-specific engagement efforts. Pediatric rare disease drug development would benefit from direct and early involvement of pediatric patients and their caregivers in determining the most relevant and clinically meaningful endpoints and outcome assessment tools for use in clinical trials.

II. Topics for Discussion at the Public Workshop

In this workshop, FDA will obtain the pediatric patient perspective on their disease/condition and what is most important to consider when designing rare disease trials. There will also be discussion regarding patients' thoughts on clinical endpoints that are currently being used in clinical trials, potential areas of innovation, and how to create processes that might include pediatric patients and their caregivers as collaborators in endpoint development in early stages of medical product development (*e.g.,* protocol design). The morning session will focus on identifying endpoints that capture important aspects of how pediatric patients feel and function. The afternoon session will focus on steps for development of clinical outcome assessment tools for use in pediatric patient populations and the potential role of child and youth friendly technology in endpoint assessments.

III. Participation in the Public Workshop

Registration: Persons interested in attending this public workshop must register online at: *https://www.eventbrite.com/e/adept-6-workshop-pediatric-clinical-trial-endpoints-for-rare-diseases-registration-67523118465* by November 5, 2019. For those without internet access, please contact Terrie Crescenzi or Elizabeth Sanford (see **FOR FURTHER INFORMATION CONTACT**) to register.

Registration is free and based on space availability, with priority given to early registrants. Onsite registration on the day of the meeting will be based on space availability. Registration information, the agenda, and additional background materials can be found at *http://wcms-internet.fda.gov/news-*