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-*

events/fda-meetings-conferences-and-workshops/advancing-development-pediatric-therapeutics-adept-6-pediatric-clinical-trial-endpoints-rare.

If you need special accommodations due to a disability, please contact Elizabeth Sanford (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance. Persons attending the meeting are advised that FDA is not responsible for providing access to electrical outlets.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. Login URL: *https://collaboration.fda.gov/adept6/.*

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 *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, FDA will post it at *http://wcms-internet.fda.gov/news-events/fda-meetings-conferences-and-workshops/advancing-development-pediatric-therapeutics-adept-6-pediatric-clinical-trial-endpoints-rare.*

Dated: October 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22187 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–2013–N–1428]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 12, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0827. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0827—Extension

The Drug Quality and Security Act added section 503B to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b) creating a category of entities called ''outsourcing facilities.'' Outsourcing facilities, as defined in section 503B(d)(4) of the FD&C Act, are facilities that must meet all the requirements described in section 503B, including registering with FDA as an outsourcing facility and submitting regular reports identifying the drugs compounded by the outsourcing facility during the previous 6-month period. The first of these reports must be submitted upon initial registration as an outsourcing facility. Thereafter, semiannual product reports must be submitted, once during the month of June and once during the month of December, for as long as an establishment remains registered as an outsourcing facility.

In addition, drug products compounded in an outsourcing facility can qualify for exemptions from the FDA approval requirements in section 505 of the FD&C Act (21 U.S.C. 355) and the requirement to label products with adequate directions for use under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) if the requirements in section 503B are met.

To help respondents understand the statutory requirements, how we interpret them, and the associated information collection, we developed the guidance document entitled ''Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' The guidance is available from our website at: *https://www.fda.gov/media/90173/download.* The guidance explains that, once an entity has elected to register as an outsourcing facility, it must submit reports identifying the drugs compounded by the outsourcing facility. The guidance also communicates who must report, the format of the report, the content to include in each report, when to report, how reports are submitted to FDA, and the consequences of outsourcing facilities' failure to submit reports.

In the **Federal Register** of July 17, 2019 (84 FR 34184), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We therefore estimate the burden of the information collection as follows: