

“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)).

Submit written requests for a single copies of this guidance entitled “How to Prepare a Pre-Request for Designation (Pre-RFD)” to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Leigh Hayes, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993-0002, 301-796-8930.

SUPPLEMENTARY INFORMATION:

I. Background

Since its establishment on December 24, 2002, OCP has served as a resource for sponsors at various stages of development of their products. Sponsors often seek OCP feedback on

whether their human medical product will be regulated as a drug, a device, a biologic, or a combination product, and which FDA medical product Agency Center (CDER, CBER, or CDRH) will regulate it, if it is a non-combination product, or will have the primary jurisdiction for the premarket review and regulation of the product, if it is a combination product.

There are two ways that a sponsor can receive such a feedback from OCP. One option is to submit an RFD to receive a formal, binding determination for the sponsor’s product with respect to classification and/or center assignment that may be changed under conditions specified in section 563 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-2) and 21 CFR 3.9 in the regulations. The RFD process is codified in 21 CFR part 3, and OCP has issued a guidance about this process (see “How to Write a Request for Designation” at <https://www.fda.gov/RegulatoryInformation/Guidances/ucm126053.htm>). A second more flexible option is for a sponsor to submit an inquiry to OCP to receive a preliminary jurisdictional assessment, which is not binding.

Many sponsors seek to utilize a more flexible, approachable way to interact with OCP and the medical product Agency Centers, to obtain feedback from the Agency before submitting a marketing application to the Agency. Over time, these informal methods of obtaining feedback have become increasingly customary with sponsors, and for some, even preferable to the formal RFD process. Accordingly, FDA is enhancing the transparency and consistency of such interaction, which will now be called the “Pre-Request for Designation (Pre-RFD) Program.”

This guidance describes this structured process with clear recommendations for sponsors wishing to submit Pre-RFDs. It also provides the process for review of Pre-RFDs by FDA staff, the general timeframes for sponsors to receive feedback from OCP, and the process for scheduling teleconferences and meetings in relation to a Pre-RFD.

FDA carefully considered the comments received on the draft guidance, and, where appropriate, has revised the guidance to reflect such comments. FDA encourages stakeholders to contact OCP if they have additional questions.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on how to prepare a Pre-RFD. 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.

II. Paperwork Reduction Act of 1995

This 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 this guidance regarding how to prepare a Pre-RFD have been approved under OMB control number 0910-0845.

III. Electronic Access

Persons with access to the internet may obtain the document at <https://www.fda.gov/RegulatoryInformation/Guidances/ucm534661.htm>.

Dated: February 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-03230 Filed 2-15-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0404]

Pediatric Medical Device Development; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled “Pediatric Medical Device Development.” The purpose of the public meeting is to identify strategies to enhance the medical device ecosystem to cultivate development and innovation of devices that serve the unique needs of pediatric populations. (The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines pediatric patients, for medical device purposes, as age 21 years or younger at the time of diagnosis or treatment and specifies categories of pediatric subpopulations.) Topics for discussion will include ways to improve research infrastructure and research networks to facilitate the conduct of clinical studies of pediatric devices, extrapolation, use of postmarket registries and data to increase pediatric medical device

labeling, assistance to medical device manufacturers in developing devices for pediatric populations, and identifying barriers to pediatric device development and incentives to address such barriers.

DATES: The public meeting will be held on August 13 and August 14, 2018, from 9 a.m. to 5 p.m. Submit either electronic or written comments on this public meeting by September 14, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration information.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Rm. 1503 (the Great Room), Silver Spring, MD 20993-0002. Entrance for the public meeting 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>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 14, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of September 14, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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-N-0404 for "Pediatric Medical Device Development; Public Meeting; Request for Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), 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](https://www.fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf).

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FOR FURTHER INFORMATION CONTACT:

Victoria Wagman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5562, Silver Spring, MD 20993, 301-796-6581, Victoria.Wagman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

For more than a decade, legislative changes and regulatory process improvements have been implemented to facilitate development of medical devices that serve the unique needs of pediatric populations. The FD&C Act defines pediatric patients, for medical device purposes, as age 21 years or younger at the time of diagnosis or treatment and specifies categories of pediatric subpopulations (see section 520(m)(6)(E) of the FD&C Act (21 U.S.C. 360j(m)(6)(E))). Nevertheless, children and those who care for them continue to have limited medical device options. FDA seeks to identify opportunities to support development and innovation of medical devices designed and labeled for children. Engaging in such opportunities will not only serve children and their families but optimize the medical device ecosystem for all. The Agency invites all stakeholders, including representatives from the medical device industry, academia, recipients of funding under section 305 of the Pediatric Medical Device Safety and Improvement Act of 2007, medical provider organizations, and organizations and individuals representing patients and consumers to collaborate with us in addressing this important public health issue (See Pub. L. 110-85; 42 U.S.C. 282 note).

FDA guidance documents entitled "Premarket Assessment of Pediatric Medical Devices," "Providing Information about Pediatric Uses of Medical Devices," and "Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices," provide background information regarding pediatric medical device development (Refs. 1 to 3).

II. Topics for Discussion at the Public Meeting

As mandated by section 502(d) of the FDA Reauthorization Act of 2017 (FDARA), this FDA meeting on the development and labeling of pediatric medical devices is being convened with representatives from the medical device industry, academia, recipients of funding under section 305 of the Pediatric Medical Device Safety and Improvement Act of 2007, medical provider organizations, and organizations representing patients and consumers (see Pub. L. 110–85; 42 U.S.C. 282 note).

As directly outlined in FDARA, the meeting shall include consideration of ways to: (1) Improve research infrastructure and research networks to facilitate the conduct of clinical studies of devices for pediatric populations that would result in the approval or clearance, and labeling of medical devices for such populations; (2) appropriately use extrapolation under section 515A(b) of the FD&C Act (21 U.S.C. 360e–1(b)); (3) enhance the appropriate use of postmarket registries and data to increase pediatric medical device labeling; (4) increase FDA assistance to medical device manufacturers in developing devices for pediatric populations that are approved or cleared, and labeled, for their use; and (5) identify current barriers to pediatric device development and incentives to address such barriers.

A detailed agenda will be posted on the following website in advance of the workshop at <https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. Select this event from the list of items provided.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at <https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (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.

Registration is free, and in-person attendance is based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by August 6, 2018, 3 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the

number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m. We will let registrants know if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Peggy Roney at the Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5231, Silver Spring, MD 20993–0002, 301–796–5671, Peggy.Roney@fda.hhs.gov, no later than June 1, 2018.

Requests for Oral Presentations: During online registration, you may indicate if you wish to present during a public comment session and which topic(s) you wish to address. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. We encourage persons who are interested in making an oral presentation during a public comment session to indicate their intent on the registration form by 3 p.m. Eastern Time on June 29, 2018. Based on the number of applicants for oral presentations, FDA will distribute the available time equally among all presenters and inform selected presenters of the public presentation agenda by July 6, 2018. If selected for presentation, any presentation materials must be emailed to Victoria Wagman at Victoria.wagman@fda.hhs.gov no later than July 13, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the public meeting: This public meeting will also be webcast. The webcast link will be available on the registration web page after August 6, 2018. Please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar (<https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>) and select this event from the list of items provided. Organizations are requested to register all participants but view using one connection per location.

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](https://www.fda.gov/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 meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.)

IV. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>.

1. FDA's guidance for Industry and FDA Staff: "Premarket Assessment of Pediatric Medical Devices," available at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089742.pdf>.

2. FDA's guidance for Industry and FDA Staff: "Providing Information about Pediatric Uses of Medical Devices," available at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM339465.pdf>.

3. FDA's guidance for Industry and FDA Staff: "Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices," available at <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm444591.pdf>.

Dated: February 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–03215 Filed 2–15–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2016–E–2512 and FDA–2016–E–2511]

Determination of Regulatory Review Period for Purposes of Patent Extension; COTELLIC

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has