information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Draft Guidance for Industry and Food and Drug Administration Staff'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and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 or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: J. Allen Hill, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5627, Silver Spring, MD 20993–0002, 301–796–7086; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

The pre-IDE program was established in 1995, to provide applicants a mechanism to obtain FDA feedback on future IDE applications prior to their submission. Over time, the pre-IDE program evolved to include feedback on PMA applications, HDE applications, de novo requests, and 510(k) submissions, as well as to address whether a clinical study requires submission of an IDE.

To capture this evolution, the Secretary of Health and Human Services' 2012 Commitment Letter to Congress regarding the Medical Device User Fee Amendments of 2012 (MDUFA III) included FDA's commitment to institute a structured process for managing these interactions, referring to them as ''Pre-Submissions.'' The Pre-Submission Guidance, published February 18, 2014, implemented the broader Q-Submission (Q-Sub) Program, which includes Pre-Submissions (Pre-Subs), as well as additional opportunities to engage with FDA.

As part of the Medical Device User Fee Amendments of 2017 (MDUFA IV), industry and the Agency agreed to refine the Q-Sub Program with changes related to the scheduling of Pre-Sub meetings and a new performance goal on the timing of FDA feedback on Pre-Subs. This guidance reflects those changes and clarifies other elements of the Q-Sub program.

This draft guidance document provides an overview of the mechanisms available to applicants through which they can request feedback from or a meeting with FDA regarding potential or planned medical device IDE applications, PMA applications, HDE applications, de novo requests, 510(k) Submissions, CLIA Waiver by Application, Accessory Classification Requests, and certain INDs and BLAs.

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 ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Draft Guidance for Industry and Food and Drug Administration Staff.'' 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 is also available at *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Draft Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1677 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance also refers to previously approved information collections 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 803 are approved under OMB control number 0910–0437; the collections of information in 21 CFR part 807, subpart E are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 are approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814 are approved under OMB control number 0910–0231; and the collections of information for ''Request for Feedback on Medical Device Submissions'' are approved under OMB control number 0910–0756.

Dated: June 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12223 Filed 6–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1823]

Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice, establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pulmonary-Allergy Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on July 25, 2018, from 8 a.m. to 4 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2018–N–1823. The docket will close on July 24, 2018. Submit either electronic or written comments on this public meeting by July 24, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 24, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of July 24, 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.

Comments received on or before July 11, 2018, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

You may submit comments 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–N–1823, for ''Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSSES**), 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.'' FDA 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 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 the 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.

FOR FURTHER INFORMATION CONTACT: Jennifer Shepherd, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *PADAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will discuss supplemental biologics license application (sBLA) 125526 for mepolizumab for injection, submitted by GlaxoSmithKline for add-on treatment to inhaled corticosteroid-based maintenance treatment for the reduction of exacerbations in patients with chronic obstructive pulmonary disease (COPD) guided by blood eosinophil counts.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 11, 2018. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the

approximate time requested to make their presentation on or before July 2, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 3, 2018.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Jennifer Shepherd (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12226 Filed 6–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Facilitation of Public-Private Dialogue to Increase Innovation and Investment in the Healthcare Sector

AGENCY: Immediate Office of the Secretary, HHS.

ACTION: Request for information.

SUMMARY: This request for information solicits public comment on a planned initiative of the Office of the Deputy Secretary of HHS to develop a workgroup to facilitate constructive, high-level dialogue between HHS leadership and those focused on innovating and investing in the healthcare industry. HHS seeks comment on how to structure a workgroup, or other form of interaction between the Department and such participants in the healthcare industry, in order to best support communication and understanding between these parties that will spur investment, increase competition, accelerate innovation, and allow capital investment in the healthcare sector to have a more significant impact on the health and wellbeing of Americans. HHS also seeks comment more broadly on opportunities for increased engagement and dialogue between HHS and those focused on innovating and investing in the healthcare industry.

DATES: Comments must be submitted within 30 days after the date of publication in the **Federal Register**.

ADDRESSES: You may submit comments in one of three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments through *http://www.regulations.gov*.

2. *By regular mail.* You may mail written comments to the following address ONLY: Immediate Office of the Secretary, Office of the Deputy Secretary, U.S. Department of Health and Human Services, *Attention: RFI Regarding Healthcare Sector Innovation and Investment Workgroup*, 200 Independence Avenue SW, Washington, DC 20201.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may mail written comments to the following address ONLY: Immediate Office of the Secretary, Office of the Deputy Secretary, U.S. Department of Health and Human Services, *Attention: RFI Regarding Healthcare Sector Innovation and Investment Workgroup*, 200 Independence Avenue SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: William Brady, (202) 690–6133.

SUPPLEMENTARY INFORMATION:

I. Background

The healthcare industry is a complex and highly regulated industry, and although significant investment occurs within the industry, innovation and investment in the healthcare industry must increase to produce more significant impact on the health and wellbeing of the American people. Through this effort, the Department intends to provide a forum for HHS leadership to engage in a dialogue with those focused on innovating and investing in the healthcare industry, such as healthcare innovation-focused companies, healthcare startup incubators and accelerators, healthcare investment professionals, healthcare-focused private equity firms, healthcare-focused venture capital firms, and lenders to healthcare investors and innovators. While HHS seeks comment on the structure and focus of the workgroup, as well as other opportunities for engagement, the Department envisions the workgroup as a forum to hear the individual perspectives of attendees and foster new and innovative approaches to tackle the complicated challenges facing the healthcare industry. The Department intends for non-HHS attendees to be diverse across the subsectors of the healthcare industry and the investment and innovation lifecycles, and for HHS attendees to be diverse across the Department in senior leadership positions. Workgroup members will not be asked to provide any reports or collaborative work product. No travel expenses, per diem, or compensation of any type will be provided to attendees.

II. Solicitation of Comments

HHS seeks comment on how to structure the workgroup in order to best support communication and understanding between these parties that will spur investment in the healthcare industry, increase competition, improve innovation, and allow capital investment in the healthcare sector to have a more significant impact on the health and wellbeing of Americans. HHS also seeks comment more broadly on opportunities for increased engagement and dialogue between HHS and those focused on innovating and investing in the healthcare industry. Specifically, HHS seeks comments addressing the following topics:

1. Specific areas of inquiry or focus for the workgroup. Should the workgroup review recent developments in health innovation and investing? Should the workgroup examine perceived barriers to innovation and competition in the healthcare industry? Should the workgroup encourage outside parties to provide HHS with information about how they are affected by HHS programs or regulatory requirements? Should the workgroup provide a forum for attendees to share their perspectives as to how the Department may improve relevant regulations, guidance, or other documents? Should the workgroup examine ways to encourage private sector investment to help combat health crises? What other areas of focus would best help the Department engage with diverse subsectors of the healthcare