DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0626]

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 take place virtually on August 31, 2020, from 10 a.m. Eastern Time to 4 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings 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-2020-N-0626. The docket will close on August 28, 2020. Submit either electronic or written comments on this public meeting by August 28, 2020. Please note that late, untimely
filed comments will not be considered. Electronic comments must be submitted on or before August 28, 2020. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 28, 2020. 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 August 17, 2020, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

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-2020-N-0626 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 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. Eastern Time and 4 p.m. Eastern Time, Monday through Friday, 240-402-7500.

• 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:

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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Philip Bautista, 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 meeting will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On August 31, 2020, the committee will discuss supplemental new drug application 209482/S-008, for TRELEGY ELLIPTA, a fixed-dose combination (fluticasone furoate, umeclidinium, and vilanterol inhalation powder oral inhalation), submitted by GlaxoSmithKline, for the following proposed labeling claim: reduction in all-cause mortality in patients with chronic obstructive pulmonary disease (COPD). The focus of the discussion will be on the efficacy data submitted to support the proposed labeling claim, including the results from the Informing the Pathway of COPD Treatment trial and the influence of inhaled corticosteroids withdrawal on the results.

FDA intends to make the meeting’s background material and pre-recorded presentations available to the public no later than 2 business days before the meeting. The pre-recorded presentations will be viewed by the committee prior to the meeting and will not be replayed on meeting day. If FDA is unable to post the background material and/or pre-recorded presentations on its website prior to the meeting, the background material and/or pre-recorded presentations will be made publicly available on FDA’s website at the time of the advisory committee meeting. The meeting will include brief summaries of the pre-recorded presentations. Background material and the link to the online teleconference meeting room will be 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. All electronic and written submissions submitted to the Docket (see ADDRESSES) on or before August 17, 2020, will be provided to the committee. Oral presentations from the public will be scheduled on August 31, 2020, between approximately 12:50 p.m. Eastern Time and 1:50 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see FOR FURTHER INFORMATION CONTACT). The notification should include 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 August 14, 2020. 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 August 17, 2020.

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 Philip Bautista (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).


Lauren K. Roth,

Associate Commissioner for Policy.

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