



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-2107]

Pulmonary-Allergy Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Pulmonary-Allergy Drugs Advisory Committee. This meeting was announced in the *Federal Register* of September 8, 2022. The amendment is being made to reflect changes in the DATES, ADDRESSES, and SUPPLEMENTARY INFORMATION portions of the document. The meeting was rescheduled to allow time for FDA to review new information submitted to the application. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Takyiah Stevenson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 240-402-2507, email: PADAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 8, 2022, 87 FR 55008, FDA announced that a meeting of the Pulmonary-Allergy Drugs Advisory Committee would be held on October 6, 2022. The following changes are being made.

(1) On page 55008, in the third column, the DATES portion of the document is changed to read as follows:

DATES: The meeting will be held virtually on November 9, 2022, from 9 a.m. to 5 p.m. Eastern Time.

(2) On page 55008, in the third column, the second paragraph and the first sentence of the third paragraph of the ADDRESSES portion of the document are changed to read as follows:

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2022-N-2107. Please note that late, untimely filed comments will not be considered. The docket will close on November 8, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 8, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before October 26, 2022, will be provided to the committee.

(3) On page 55009, in the third column, the first paragraph of the *Procedure* section of the SUPPLEMENTARY INFORMATION portion of the document is changed to read as follows:

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 October 26, 2022, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Eastern Time. 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 October 26, 2022. 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 October 27, 2022.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: October 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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