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 requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Patricia Love, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 32, Rm. 5129, Silver Spring, MD 20993, 301–796–8930, *Patricia.Love@fda.hhs.gov* or *combination@fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled ''Application of Human Factors Engineering Principles for Combination Products: Questions and Answers.'' This guidance provides questions and answers for industry and FDA staff on the application of HFE principles to the development of combination products as defined under 21 CFR part 3. This guidance should be used in conjunction with the guidance for industry and FDA staff ''Applying Human Factors and Usability Engineering to Medical Devices'' (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices*) and with the guidance for industry ''Safety Considerations for Product Design to Minimize Medication Errors'' (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-considerations-product-design-minimize-medication-errors-guidance-industry*).

This guidance focuses on considerations for the application of HFE principles to combination products comprised of a medical device combined with a drug or a biological product submitted for review in the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, or the Center for Drug Evaluation and Research. This guidance discusses, among other things, the definition of a combination product critical task, considerations for combination products due to the use of a drug or biological product constituent part together with a device constituent part, training as part of the user interface, and human factors (HF) validation data to support the combination product user interface that may be included in a premarket submission.

This guidance finalizes the draft guidance entitled ''Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development'' issued on February 3, 2016 (81 FR 5764). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include: change in format to a questions and answers format, deletion of HF information that is redundant with other FDA guidance documents and focusing the guidance on combination product specific issues, providing additional information in response to comments, clarification of the combination product critical task definition, further explanation of considerations to help identify combination product critical tasks, and replacement of an appendix of examples of user task failures with examples that provide a contextual discussion of combination product critical task considerations. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Application of Human Factors Engineering Principles for Combination Products: Questions and Answers.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information for 21 CFR part 312 for investigational new drug applications have been approved under OMB control number 0910–0014 and the collections of information for 21 CFR part 812 for investigational device exemptions have been approved under OMB control number 0910–0078. The collections of information in 21 CFR part 314 for new drug applications have been approved under OMB control number 0910–0001 and the collections of information in 21 CFR part 601 for biologics license applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 814, subparts A through E for premarket approval applications have been approved under OMB control number 0910–0231. The collections of information in 21 CFR part 807, subpart E for premarket notifications have been approved under OMB control number 0910–0120 and the collections of information in 21 CFR 860, subpart D for De Novo classifications have been approved under OMB control number 0910–0844.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/combination-products/guidance-regulatory-information/combination-products-guidance-documents, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19404 Filed 9–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0984]

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 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 November 17, 2023, from 9 a.m. to 5 p.m. Eastern Time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing 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–2023–N–0984. The docket will close on November 16, 2023. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 16, 2023. 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 November 2, 2023, 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–2023–N–0984 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. and 4 p.m., 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: *https://www.govinfo.gov/content/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, 240–402–7500.

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). 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 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 the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. The Committee will discuss new drug application 215010, for gefapixant oral tablets, submitted by Merck Sharp & Dohme Corp., for the proposed indication of treatment of adults with refractory or unexplained chronic cough.

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 on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views,

orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before November 2, 2023, 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 25, 2023. 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 26, 2023.

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 Takyiah Stevenson (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. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. No participant will be prejudiced by this waiver, and that the ends of justice will be served by allowing for this modification to FDA's advisory committee meeting procedures.

Dated: September 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19407 Filed 9–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3137]

Endpoints and Trial Designs To Advance Drug Development in Kidney Transplantation; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the following public meeting on ''Endpoints and Trial Designs To Advance Drug Development in Kidney Transplantation.''

DATES: The public meeting will be held on November 9, 2023, from 8 a.m. to 4:30 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), 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/about-fda/visitor-information.*

FOR FURTHER INFORMATION CONTACT: Ozlem Belen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 22, Rm. 6118, Silver Spring, MD 20993–0002, 301–796–0676.

SUPPLEMENTARY INFORMATION:

I. Background

The goal of this public meeting is to facilitate discussion among FDA, academicians, and industry representatives on endpoint and trial designs to promote drug development in kidney transplantation. The last drug FDA approved for use in prophylaxis of organ rejection in kidney transplant was belatacept in 2011. It is well established that kidney transplantation offers a clear survival and quality-of-life advantage to patients with end-stage kidney disease. The current treatment options have resulted in excellent short-term graft and patient survival but not without long-term side effects. FDA recognizes the importance of offering safe and effective drugs with a tolerable adverse effect profile to preserve kidney allografts for patients. This public meeting aims to discuss current and future potential endpoints and trial designs that can promote development in this area of unmet need.

II. Topics for Discussion at the Public Meeting

The topics of discussion include:

- Efficacy endpoints for prophylaxis of kidney transplant rejection trials: current state of primary endpoints and future potential endpoints.
- Biopsy proven acute rejection efficacy failure: long-term impact, impact of treatment, and grade of rejection.
- Noninferiority trials: identifying clinically important noninferiority margin, safety, and secondary efficacy endpoints.
- Enrichment as a tool in trial design: identifying target populations.

III. Attending the Public Meeting

Registration: If you wish to attend the public meeting (either in person or via Zoom), please register by October 26, 2023, at 4 p.m. Eastern Time. Visit the registration page here: *https://kidney-transplantation-workshop.eventbrite.com.*

Registration is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 7:30 a.m. Eastern Time. We will let registrants know if registration closes before the day of the public meeting/public workshop.

If you need special accommodations due to a disability, please contact *ONDPublicMTGSupport@fda.hhs.gov* no later than October 18, 2023.

Streaming Webcast of the Public Meeting: This public meeting will also be virtual via Zoom. Zoom links will be sent using the email provided by persons who register. We will post a link to the archived recording on *http://wcms-internet.fda.gov/drugs/news-events-human-drugs/endpoints-and-trial-designs-advance-drug-development-kidney-transplantation-11092023?check_logged_in=1*