

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2022-N-1745]

**Vaccines and Related Biological Products 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 Vaccines and Related Biological Products Advisory Committee (VRBPAC). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. This meeting will be held to discuss the Strain Selection for the 2023 Southern Hemisphere Influenza Season. 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 virtually on October 6, 2022, from 8:30 a.m. to 12:40 p.m. Eastern Time.

**ADDRESSES:** Please note that due to the impact of the COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. The online web conference meeting will be available at the following link on the day of the meeting at: <https://youtu.be/qazitjMHZK4>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2022-N-1745. The docket will close on October 5, 2022. Either electronic or written comments on this public meeting must be submitted by September 29, 2022. 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 October 5, 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 September 28, 2022, will be provided to the committee. Comments received after September 28, 2022, and by October 5, 2022, will be taken into consideration by FDA. In the event that the meeting is canceled, 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-2022-N-1745 for "Vaccines and Related Biological Products Advisory Committee (VRBPAC); 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., 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: <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:** Sussan Paydar or Prabhakara Atreya, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993-0002, 240-506-4946, [CBERVRBPAC@fda.hhs.gov](mailto:CBERVRBPAC@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 presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On October 6, 2022, the committee will meet in open session to discuss the Strain Selection for the Influenza Virus Vaccines for the 2023 Southern Hemisphere Influenza Season.

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 time 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. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

*Procedure:* On October 6, 2022, from 8:30 a.m. to 12:40 p.m. EasternTime, the meeting is open to the public. 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 September 28, 2022, will be provided to the committee. Comments received after September 28, 2022, and by October 5, 2022, will be taken into consideration by FDA. Oral presentations from the public will be scheduled between approximately 10:40 a.m. and 11:40 a.m. EasternTime. 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, along with their names, email addresses, and direct contact phone numbers of proposed participants, on or before 12 p.m. Eastern Time on September 21, 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 6 p.m. September 22, 2022.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto: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 Sussan Paydar or Prabhakara Atreya (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: August 15, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-17784 Filed 8-17-22; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Office of the Director, National Institutes of Health; Amended Notice of Meeting**

Notice is hereby given of a change in the meeting of the Council of Councils, September 8, 2022, 10:30 a.m. to September 9, 2022, 03:00 p.m., virtual meeting which was published in the **Federal Register** on, August 8, 2022, FR Doc 2022-16892, 87 FR 48189.

The notice is being amended to change the start and end times of the open portion of the meeting on September 8, 2022 from 10:30 a.m. to 10:15 a.m. and end time 3:00 p.m. to 3:30 p.m. and change the end time of the open portion of the meeting on September 9, 2022 from 3:10 p.m. to 3:15 p.m.

Dated: August 12, 2022.

**David W Freeman,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2022-17726 Filed 8-17-22; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Government-Owned Inventions; Availability for Licensing**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**FOR FURTHER INFORMATION CONTACT:**

Dawn Taylor-Mulneix at 301-767-5189, or [dawn.taylor-mulneix@nih.gov](mailto:dawn.taylor-mulneix@nih.gov). Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

**SUPPLEMENTARY INFORMATION:**

**SARS-CoV-2 Infection of Human Lung Epithelial Cells Triggers a Cell-Mediated Acute Fibrin Fibrosis**

*Description of Technology*

Scientists at National Institute of Allergy and Infectious Diseases (NIAID) have developed a method of treatment for virus-induced lung fibrosis using nebulized thrombin inhibitors. Since March 2020, the World Health Organization (WHO) estimates that 564 million people have been infected with SARS-CoV-2 world-wide. Lung fibrosis is a major factor associated with SARS-CoV-2 infections and can contribute to mortality. Additionally, severe SARS-CoV-2 cases can result in long-term pulmonary disease due to lung fibrosis. At present, attempts to treat lung fibrosis developed during a SARS-CoV-2 infection using intravenous heparin have been unsuccessful.

NIAID scientists have discovered a previously unknown acute fibrosis mechanism mediated by SARS-CoV-2 infected primary lung epithelium, and have developed an innovative method of treating lung fibrosis using nebulized thrombin inhibitors.

This technology is available for licensing for commercial development