FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3975	24	1	24	.17 (10 minutes)	4

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: June 26, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–12922 Filed 7–10–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–FDA–2025–N–0008]

Request for Nominations for Voting Members on the Tobacco Products Scientific Advisory Committee

Correction

In notice document 2025–11600, appearing on page 27023, in the issue of Wednesday, June 25, 2025, in the first column, in the **DATES** section, in the second line, ''June 25, 2025'' is corrected to read ''August 25, 2025''.

[FR Doc. C1–2025–11600 Filed 7–10–25; 8:45 am]

BILLING CODE 0099–10–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Advisory Council.

Date: August 20, 2025.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Charisee Lamar, Ph.D., M.P.H., R.R.T., Division Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 206–Q, Bethesda, MD 20892–7924, (301) 827–5517, *lamarc@mail.nih.gov*.

Information is also available on the Institute's/Center's home page: *https://www.nhlbi.nih.gov/about/advisory-and-peer-review-committees/advisory-council* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: July 9, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–13010 Filed 7–10–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cardiovascular Sciences.

Date: August 6–7, 2025.

Time: 8:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Michael L. Bloom, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7804, Bethesda, MD 20892, 301–451–0132, *bloomm2@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neurotechnology, Devices, Applications and Treatment.

Date: August 7–8, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Steven G. Britt, MD, Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892, (301) 480–1953, *steve.britt@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: Advancing Translation of Long-Acting Strategies for HIV and HIV-Associated Co-infections (AT LAST).

Date: August 7, 2025.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Kristina S. Wickham, Ph.D., Scientific Review Officer, NIAID/DEA/SRP, BG 5601FL, RM 3G22B, 5601 Fishers Ln., Rockville, MD 20852, (301) 761–5390, *kristina.wickham@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Circulation Sciences.

Date: August 12, 2025.

Time: 9:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Nakia C. Brown, Ph.D., Scientific Review Officer, Office of Grants Management and Scientific Review, National Ctr for Advancing Translational Sciences, 6701 Democracy Blvd., Bethesda, MD 20892, 301–827–4905, *brownnac@mail.nih.gov*.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Analytics and Statistics for Population Research Panel B Study Section.

Date: August 12–13, 2025.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Varsha Shukla, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Science, 530 Davis Dr., Keystone Bldg., Room 3094, Durham, NC 27713, 984–287–3288, *Varsha.shukla@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–AI–24–067 Radiation Injuries, Medical Countermeasures, and Development of Alternative Human Models.

Date: August 12, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Irene Ramos Lopez, Scientific Review Officer, The Center for Scientific Review, The National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, *irene.ramoslopez@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business- Anti-Infective Therapeutics.

Date: August 14, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Samita Sarkar Andreansky, Scientific Review Officer, NIAID, AIDS Review Branch, BG 5601 Fishers Lane, RM 3E71, MSC 9834, 5601 Fishers Ln., Bethesda, MD 20892, (240) 669–2915, *samita.andreansky@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Neuroscience.

Date: August 15, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jingshan Chen, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NIDCR, Bethesda, MD 20892, (301) 451–2405, *jingshan.chen@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 8, 2025.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–12931 Filed 7–10–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning Pirfenidone Tablets

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection (CBP) has issued a final determination concerning the country of origin of pirfenidone tablets. Based upon the facts presented, CBP has concluded that the pirfenidone tablets would be the product of a foreign country or instrumentality designated pursuant to 19 U.S.C. 2511(b).

DATES: The final determination was issued on June 24, 2025. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination no later than August 11, 2025.

FOR FURTHER INFORMATION CONTACT: Jordan Higgins, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, at (202) 325–1134.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on June 24, 2025, U.S. Customs and Border Protection (CBP) issued a final determination concerning the country of origin of pirfenidone tablets for purposes of Title III of the Trade Agreements Act of 1979. This final determination, Headquarters Ruling Letter (HQ) H342828, was issued at the request of Alembic Pharmaceuticals, Inc. under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–18). In the final determination, CBP has concluded that, based upon the facts presented, the country of origin of the pirfenidone tablets is the country of origin of the active pharmaceutical ingredient (API), which is Italy.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination shall be published in the **Federal Register** within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the **Federal Register**.

Alice A. Kipel,

Executive Director, Regulations and Rulings, Office of Trade.

90 K Street NE – 10th Floor
Washington, DC 20229-1177

U.S. Customs and Border Protection

HQ H342828

June 24, 2025

OT:RR:CTF:VS H342828 JH

CATEGORY: Origin

Gregory S. McCue, Steptoe, 1330 Connecticut Ave. NW, Washington, DC 20036–1795

Re: U.S. Government Procurement; Country of Origin of Pirfenidone Tablets

Dear Mr. McCue:

This is in response to your request, dated October 8, 2024, on behalf of Alembic Pharmaceuticals, Inc. (''Alembic''), for a final determination concerning the country of origin of pirfenidone tablets pursuant to Title III of the Trade Agreements Act of 1979 (''TAA''), as amended (19 U.S.C. 2511 *et seq.*), and subpart B of Part 177, U.S. Customs and Border Protection (''CBP'') Regulations (19 CFR 177.21, *et seq.*). Alembic is a party-at-interest within the meaning of 19 CFR 177.22(d)(1) and 177.23(a) and is therefore entitled to request this final determination.

Facts

The articles under consideration are pirfenidone tablets. The tablets are used for the treatment of idiopathic pulmonary fibrosis (scarring of the lungs with an unknown cause). The tablets have one active pharmaceutical ingredient (''API'') that is manufactured in Italy and shipped to India for final processing which includes mixing with inactive materials, forming tablets, and packaging. Specifically, the tablets are manufactured in a seven-step process in India:

(1) The API pirfenidone is sifted along with three inactive ingredients: microcrystalline cellulose, croscarmellose sodium, and povidone.

(2) Wet granulation is employed. This process includes rapid mixer granulator