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

dry mixing, adding a binder (purified water), and kneading.

(3) The mixture is screened and dried in a fluid bed dryer.

(4) The mixture undergoes sifting through a vibratory sifter and milling of retain granules through a multimill machine. Afterwards, the mixture undergoes sifting of extra granular material with lubricants including microcrystalline cellulose, colloidal silicon dioxide, and magnesium stearate.

(5) The dry mixture is pre-lubricated and lubricated in a conta blender.

(6) The final mixture is compressed into tablets, which is then sprayed with a coating of ''Opadry'' and purified water.

(7) The final tablets are packaged and imported into the United States.

Issue

What is the country of origin of the pirfenidone tablets for purposes of U.S. Government procurement?

Law and Analysis

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purpose of granting waivers of certain ''Buy American'' restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 CFR 177.21 *et seq.,* which implements Title III, Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–2518).

CBP's authority to issue advisory rulings and final determinations stems from 19 U.S.C. 2515(b)(1), which states:

> For the purposes of this subchapter, the Secretary of the Treasury shall provide for the prompt issuance of advisory rulings and final determinations on whether, under section 2518(4)(B) of this title, *an article is or would be a product of a foreign country or instrumentality designated pursuant to section 2511(b) of this title.*

Emphasis added.

The Secretary of the Treasury's authority mentioned above, along with other customs revenue functions, are delegated to the Secretary of Homeland Security via Treasury Department Order (TO) 100–20 ''Delegation of Customs revenue functions to Homeland Security,'' dated October 30, 2024, and are subject to further delegations to CBP (*see also* 19 CFR part 177, subpart B).

The rule of origin set forth in 19 U.S.C. 2518(4)(B) states:

> An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 CFR 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with the Federal Acquisition Regulation (''FAR''). *See* 19 CFR 177.21. In this regard, CBP recognizes that the FAR restricts the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 CFR 25.403(c)(1).

The FAR, 48 CFR 25.003, defines ''designated country end product'' as:

> a WTO GPA [World Trade Organization Government Procurement Agreement] country end product, an FTA [Free Trade Agreement] country end product, a least developed country end product, or a Caribbean Basin country end product.

Section 25.003 defines ''WTO GPA country end product'' as an article that:

> (1) Is wholly the growth, product, or manufacture of a WTO GPA country; or
>
> (2) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in a WTO GPA country into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product includes services (except transportation services) incidental to the article, provided that the value of those incidental services does not exceed that of the article itself.

We note that the API is produced in Italy and the tablet formulation occurs in India. Italy is a TAA-designated country, and India is not.

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, CBP has generally held that the processing of pharmaceutical products from bulk form into measured doses does not result in a substantial transformation of the product. *See, e.g.,* Headquarters Ruling (''HQ'') 561975, dated April 3, 2002; HQ 561544, dated May 1, 2000; HQ 735146, dated November 15, 1993; HQ H267177, dated November 5, 2016; HQ H233356, dated December 26, 2012; and, HQ 561975, dated April 3, 2002.

In HQ 289702, dated January 30, 2018, concerning the country of origin of Levetiracetam tablets, the API underwent coating, mixing with inactive ingredients, blending, and compression. CBP determined that the API retained its physical and chemical properties through the processing that was performed. Therefore, the API did not undergo a substantial transformation. Additionally, in HQ 243567, dated July 26, 2013, concerning the country of origin of Dificid tablets, the API was mixed with various other ingredients via a wet granulation process and was then compressed into tablets that were then coated. CBP did not find that the API underwent a substantial transformation and determined that the country of origin was where the API originated from as the API imparts the essential character of the goods.

Consistent with the cases above, the processing in India does not result in a change in the medicinal use of the finished tablets, the API retains its chemical and physical properties, and it is merely put into a tablet form and packaged. Accordingly, we find that no substantial transformation occurs in India, and the imported tablets would be of the same country of origin as the API, which is Italy.

Holding

The country of origin of the pirfenidone tablets for purposes of U.S. Government procurement is Italy.

Notice of this final determination will be given in the **Federal Register**, as required by 19 CFR 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 CFR 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 CFR 177.30, any party-at-interest may, within 30 days of publication of the **Federal Register** Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel,

Executive Director, Regulations & Rulings, Office of Trade.

[FR Doc. 2025–12965 Filed 7–10–25; 8:45 am]

BILLING CODE 9111–14–P