UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN PHOTODYNAMIC THERAPY SYSTEMS, COMPONENTS THEREOF, AND PHARMACEUTICAL PRODUCTS USED IN COMBINATION WITH THE SAME**	**Investigation No. 337-TA-1411**

NOTICE OF A COMMISSION DETERMINATION TO EXTEND THE DATE FOR DETERMINING WHETHER TO REVIEW A FINAL INITIAL DETERMINATION AND THE TARGET DATE FOR COMPLETION OF THE INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that in view of the shutdown of the Federal Government, the U.S. International Trade Commission has determined to extend the date for determining whether to review a final initial determination ("FID") to January 29, 2026, and the target date for completion of the investigation to March 30, 2026.

FOR FURTHER INFORMATION CONTACT: B. Rashmi Borah, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2518. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. For help accessing EDIS, please email *EDIS3Help@usitc.gov*. General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on August 1, 2024, based on a complaint filed by Sun Pharmaceutical Industries, Inc. ("Complainant") of Princeton, New Jersey. 89 FR 62790 (Aug. 1, 2024). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based on the importation into the United States, the sale for importation, and the sale within the United States after importation of certain photodynamic therapy systems, components thereof, and pharmaceutical products used in combination with the same by reason of infringement of certain claims of the U.S. Patent Nos. 11,446,512 ("the '512 patent") and 11,697,028 (collectively, "the Asserted Patents"). *Id*. The complaint further alleges that a domestic industry exists or is in the process of being established. *Id*. The notice of investigation

names four respondents: (1) Biofrontera Inc. of Woburn, Massachusetts; (2) Biofrontera Pharma GmbH of Leverkusen, Germany; (3) Biofrontera Bioscience GmbH of Leverkusen, Germany; and (4) Biofrontera AG of Leverkusen, Germany (collectively, "Respondents"). *Id*. The Office of Unfair Import Investigations is not a party to this investigation. *Id*.

On November 20, 2024, the Commission amended the complaint and notice of investigation to add infringement allegations as to claims 17 and 18 of the '512 patent. Order No. 8 (Oct. 22, 2024), *unreviewed by* Comm'n Notice (Nov. 20, 2024).

On June 25, 2025, the ALJ issued Order No. 23 granting pursuant to Commission Rule 210.18 (19 CFR 210.18) Complainant's motion for summary determination that it has satisfied the economic prong of the domestic industry requirement.

On July 25, 2025, the Commission determined to review Order No. 23. Comm'n Notice at 2 (July 25, 2025).

On September 30, 2025, the ALJ issued the FID, finding a violation of section 337. The FID also includes the ALJ's recommended determination ("RD") on remedy, the public interest, and bonding, should the Commission find a violation of section 337. Specifically, the RD recommends entry of a limited exclusion order against Respondents' infringing products, entry of a cease and desist orders against Respondents, and a bond of zero percent for any importations of infringing products during the period of Presidential review.

On November 17, 2025, the parties filed their respective petitions for review of the FID. On November 25, 2025, the parties filed their respective responses.

Prior to the lapse in appropriations, the deadline for determining whether to review the FID was December 1, 2025, and the target date for completion of the investigation was February 2, 2026. In view of the shutdown of the Federal Government, the Commission has determined to extend the date for determining whether to review the FID to January 29, 2026, and to extend the target date for completion of the investigation to March 30, 2026.

The Commission vote for this determination took place on December 17, 2025.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR Part 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: December 17, 2025