

Facility	Provider No.	Date of initial certification	Date of re-certification	State
Summa Health, 95 Arch Street, Suite 205, Akron, OH 44304; <i>Other information:</i> DNV ID #: C738012; <i>Previous Re-certification Dates:</i> 11/16/2021.	360020	11/16/2021	11/07/2024	OH
Westchester Health Care Corporation, 100 Woods Road, Valhalla, NY 10595; <i>Other information:</i> Joint Commission ID #2518; <i>Previous Re-certification Dates:</i> 11/19/2009; 11/15/2011; 12/03/2013; 12/08/2015; 12/19/2017; 03/07/2020; 06/30/2022.	330234	11/19/2009	09/25/2024	NY
Scott & White Memorial Hospital, 2401 S 31st St., Temple, TX 76508-0001; <i>Other information:</i> Joint Commission ID #9241; <i>Previous Re-certification Dates:</i> 12/07/2011; 12/03/2013; 01/12/2016; 12/19/2017; 03/05/2020; 07/02/2022.	450054	12/07/2011	09/06/2024	TX

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (October Through December 2024)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. For the purposes of this quarterly notice, there are no additions and deletions to a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. This information is available at www.cms.gov/MedicareApprovedFacilities/LVRS/list.asp#TopOfPage.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (October Through December 2024)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary

for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one comorbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilities/BSF/list.asp#TopOfPage.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (October Through December 2024)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at www.cms.gov/MedicareApprovedFacilities/PETDT/list.asp#TopOfPage.

For questions or additional information, contact David Dolan, MBA (410-786-3365).

[FR Doc. 2025-02787 Filed 2-18-25; 8:45 am]

BILLING CODE 4120-01-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1352]

Certain Selective Thyroid Hormone Receptor-Beta Agonists, Processes for Manufacturing or Relating to Same, and Products Containing Same; Notice of a Commission Determination To Review a Final Initial Determination Finding a Violation of Section 337; Request for Written Submissions on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("Commission") has determined to review a final initial determination ("FID") issued by the presiding Chief Administrative Law Judge ("Chief ALJ"), finding a violation of section 337 of the Tariff Act of 1930, as amended. The Commission requests written submissions from the parties, interested government agencies, and other interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below.

FOR FURTHER INFORMATION CONTACT:

Houda Morad, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708-4716. 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 on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation

on February 9, 2023, based on a complaint, as supplemented, filed by Viking Therapeutics, Inc. (“Viking” or “Complainant”) of San Diego, California. 88 FR 8455–56 (Feb. 9, 2023). The complaint alleges a violation of section 337 the Tariff Act, as amended, 19 U.S.C. 1337, by way of the importation, sale for importation, or sale in the United States after importation of certain selective thyroid hormone receptor-beta agonists, processes for manufacturing or relating to same, and products containing same by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure a domestic industry or prevent the establishment of a domestic industry. *Id.* The notice of investigation named the following as respondents: Asclepis Pharma Inc. of Hangzhou, Zhejiang Province, China; Asclepis Pharmaceuticals Co. of Shaoxing, Zhejiang Province, China; Asclepis Bioscience Co. of Hangzhou, Zhejiang Province, China; Gannex Pharma Co. of Shanghai, China; and Jinzi Jason Wu of Seattle, Washington (collectively, “Respondents”). *Id.* The Office of Unfair Import Investigation (“OUII”) is also participating in the investigation. *Id.*

On September 22, 2023, the Commission granted a motion to intervene filed by Foster, Murphy, Altman & Nickel, PC for the “limited purpose of defending Foster Murphy and its attorneys’ interests in response to Complainant Viking Therapeutics, Inc.’s Omnibus Motion for Sanctions.” See Order No. 37 (Aug. 28, 2023), *unreviewed by Comm’n Notice* (Sept. 22, 2023).

The Chief ALJ held an evidentiary hearing from November 13 to 16, 2023.

On October 3, 2024, the Chief ALJ issued the FID finding a violation of section 337. Specifically, the FID finds that: (1) the Commission has statutory authority to conduct this investigation; (2) the asserted trade secrets are protectable; (3) Respondents misappropriated the asserted trade secrets; (4) Complainant has demonstrated both that a domestic industry exists and is in the process of being established; and (5) Respondents’ unfair acts have caused actual and threatened injury to Viking’s domestic industry. The FID also grants Complainant’s motion for sanctions under Commission Rule 210.33 (19 CFR 210.33) and imposes certain non-monetary and monetary sanctions against Respondents and/or their former counsel (Rimon PC) jointly and severally.

The ALJ’s recommended determination (“RD”) recommends,

should the Commission find a violation of section 337, that the Commission issue: (1) a seven-year limited exclusion order against certain selective thyroid hormone receptor-beta agonists, processes for manufacturing or relating to same, and products containing same that are imported by or on behalf of Respondents; and (2) a cease and desist order against each of Respondents. The RD also recommends that the Commission impose a 100 percent bond against accused articles imported during the period of Presidential review. Regarding the public interest, the RD finds that the statutory public interest factors do not weigh against the issuance of remedial orders.

On November 8, 2024, Respondents, Rimon PC (Respondents’ former counsel), and OUII petitioned for Commission review of the FID. On the same day, Complainant filed a contingent petition for review of the FID. More specifically, Respondents request Commission review of the FID’s findings with respect to: (1) the Commission’s statutory authority over Dr. Wu, who is the Chief Executive Officer or President of each of the corporate respondents; (2) sanctions against Respondents and their former counsel, Rimon PC; (3) misappropriation of trade secrets; and (4) injury to a domestic industry. Rimon PC also petitions for Commission review of the sanctions order against Respondents and their former counsel. Additionally, OUII petitions for review of: (1) the Chief ALJ’s failure to issue an ID at the conclusion of the 100-day proceeding; (2) the FID’s findings regarding the existence and misappropriation of trade secrets; and (3) the FID’s findings regarding the existence and injury to a domestic industry. Lastly, Complainant contingently petitions for review of the FID’s findings with respect to: (1) misappropriation of trade secrets; (2) existence of a domestic industry and injury thereto; and (3) sanctions against Respondents and their former counsel.

On November 27, 2024, the parties filed responses to the petitions.

On November 4, 2024, Complainant filed a statement on the public interest pursuant to Commission Rule 210.50 (19 CFR 210.50). Respondents did not submit a statement on the public interest pursuant to Commission Rule 210.50. In addition, the Commission did not receive any submissions from the public in response to its post-RD **Federal Register** notice. See 89 FR 82256–57 (Oct. 10, 2024).

Having reviewed the record of the investigation, including the final ID, the parties’ submissions to the Chief ALJ,

and the parties’ submissions to the Commission, the Commission has determined to review the FID in its entirety.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia*, (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337–TA–360, USITC Pub. No. 2843, Comm’n Op. at 7–10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and cease and desist orders would have on: (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.¹ In particular, there is interest in responses to the following public interest questions:

1. Please address with support from the evidentiary record to what extent do the statutory public interest factors set forth in 19 U.S.C. 1337(c), especially that related to public health and welfare, weigh against the issuance of an exclusion order for a violation under 19 U.S.C. 1337(a)(1)(A) directed to the accused drug candidates in this investigation. In answering this question, identify how many people in the United States have been diagnosed with non-alcoholic steatohepatitis

¹ Commissioner Johanson does not join Commission questions 2 and 3 to the extent they seek briefing related to the FDA “safe harbor” provision of 35 U.S.C. 271(e)(1) because it is not the basis of the alleged violation in this investigation.

(“NASH”), the health implications of NASH (including the extent to which that condition can be life-threatening or raise other serious health concerns), and available treatment options.

2. Please explain with support from the evidentiary record if and how the Commission can tailor its remedy to minimize harm to the public interest. In particular, address whether the importation of accused products found in violation of 19 U.S.C. 1337(a)(1)(A) should nonetheless be permitted for purposes of ongoing or planned clinical trials. *Cf.* 35 U.S.C. 271(e)(1); *Amgen Inc. v. Int’l Trade Comm’n*, 565 F.3d 846, 848 (Fed. Cir. 2009). If an exemption is made to allow importation for purposes of clinical trials, please propose specific language in the Commission’s remedial orders reflecting such an exemption and the scope/duration of such exception.

3. Please address how a finding of violation based on the alleged trade secret misappropriation in this case might raise different public interest issues than the policy considerations underlying the FDA “safe harbor” provision of 35 U.S.C. 271(e)(1).

4. Please address with support from the evidentiary record the extent to which Madrigal Pharmaceuticals’ resmetirom product, which has been approved by the FDA for treatment of NASH, is effective for the treatment of NASH and the extent to which Viking’s VK2809 drug candidate or Ascleitis’s ASC41 and ASC43F drug candidates (the accused products) are likely to offer more effective treatment for NASH. In answering this question, explain the extent to which the patient population undergoing treatment for NASH with resmetirom overlaps with the potential patient populations for Viking’s VK2809 drug candidate or Ascleitis’s ASC41 and ASC43F drug candidates.

5. Please address the extent to which resmetirom is available to meet demand for treatment of NASH. Please address the extent to which resmetirom together with Viking’s VK2809 drug candidate if approved would be available to meet demand for treatment of NASH. Would there be a shortfall in the availability to meet demand if Ascleitis’s ASC41 and ASC43F drug candidates are excluded?

6. Please address with support from the evidentiary record how many patients in the United States are currently enrolled in or are expected to be enrolled in clinical trials for Viking’s VK2809 drug candidate during the next seven years. Please identify the current status of each clinical trial involving Viking’s VK2809 drug candidate, including when each clinical trial began (or is expected to begin), how many

patients are enrolled in each trial, and when each clinical trial will end (or is expected to end). Would this answer change depending on whether Ascleitis’s products are excluded?

7. Please address with support from the evidentiary record how many patients in the United States are currently enrolled in or are expected to be enrolled in clinical trials for Ascleitis’s ASC41 and ASC43F drug candidates during the next seven years assuming the absence of an exclusion order? Please identify the current status of each clinical trial involving Ascleitis’s ASC41 and ASC43F drug candidates, including when each clinical trial began (or is expected to begin), how many patients are enrolled in each trial, and when each clinical trial will end (or is expected to end).

8. Please address with support from the evidentiary record what impact an exclusion of the accused products will have on patients with NASH that are currently or later enrolled in clinical trials involving Ascleitis’s ASC41 and ASC43F drug candidates. Explain the extent to which patients currently or later enrolled in clinical trials involving Ascleitis’s ASC41 and ASC43F drug candidates can switch to Viking’s VK2809 drug candidate, resmetirom, or any other clinical treatment for NASH.

9. To the extent the information requested above does not exist in the evidentiary record or emerged after the close of the evidentiary record, please provide such information with a citation to the source of that information.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission’s determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the Chief ALJ on remedy, bonding, and the public interest.

In its initial submission, Complainant is also requested to identify the remedy sought and Complainant and OUII are requested to submit proposed remedial orders for the Commission’s consideration. Complainant is further requested to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and proposed remedial orders must be filed no later than close of business on February 28, 2025. Reply submissions must be filed no later than the close of business on March 7, 2025. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission’s paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (Mar. 19, 2020). Submissions should refer to the investigation number (Inv. No. 337–TA–1352) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf). Persons with questions regarding filing should contact the Secretary, (202) 205–2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed with the Commission and served on any parties to the investigation within two business days of any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records

of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. appendix 3; or (ii) by U.S. Government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on February 12, 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.

Issued: February 12, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025-02759 Filed 2-18-25; 8:45 am]

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INTERNATIONAL TRADE COMMISSION

[Investigation No. 731-TA-1733 (Preliminary)]

Methylene Diphenyl Diisocyanate (MDI) From China; Institution of Antidumping Duty Investigation and Scheduling of Preliminary Phase Investigation

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of an investigation and commencement of preliminary phase antidumping duty investigation No. 731-TA-1733 (Preliminary) pursuant to the Tariff Act of 1930 ("the Act") to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of methylene diphenyl diisocyanate (MDI products) from China, provided for in subheadings 2929.10.80 and 3909.31.00. Subject merchandise may also be entered under subheadings 3506.91.50, 3815.90.50, 3824.99.29, 3824.99.93, 3909.50.50, 3911.90.45, 3920.99.50, and 3921.13.50 of the Harmonized Tariff Schedule of the United States, that are alleged to be

sold in the United States at less than fair value. Unless the Department of Commerce ("Commerce") extends the time for initiation, the Commission must reach a preliminary determination in antidumping duty investigations in 45 days, or in this case by March 31, 2025. The Commission's views must be transmitted to Commerce within five business days thereafter, or by April 7, 2025.

DATES: February 12, 2025.

FOR FURTHER INFORMATION CONTACT:

Lawrence Jones ((202) 205-3358), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION:

Background.—This investigation is being instituted, pursuant to section 733(a) of the Tariff Act of 1930 (19 U.S.C. 1673b(a)), in response to a petition filed on February 12, 2025, by the MDI Fair Trade Coalition consisting of BASF Corporation, Florham Park, New Jersey; and The Dow Chemical Company, Midland, Michigan.

For further information concerning the conduct of this investigation and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Participation in the investigation and public service list.—Persons (other than petitioners) wishing to participate in the investigation as parties must file an entry of appearance with the Secretary to the Commission, as provided in §§ 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties

to this investigation upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in this investigation available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigation under the APO issued in the investigation, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—The Office of Investigations will hold a staff conference in connection with the preliminary phase of this investigation beginning at 9:30 a.m. on Wednesday, March 5, 2025. Requests to appear at the conference should be emailed to preliminaryconferences@usitc.gov (DO NOT FILE ON EDIS) on or before noon on Monday, March 3, 2025. Please provide an email address for each conference participant in the email. Information on conference procedures, format, and participation, including guidance for requests to appear as a witness via videoconference, will be available on the Commission's Public Calendar (Calendar (USITC) | United States International Trade Commission). A nonparty who has testimony that may aid the Commission's deliberations may request permission to participate by submitting a short statement.

Written submissions.—As provided in §§ 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before 5:15 p.m. on March 10, 2025, a written brief containing information and arguments pertinent to the subject matter of the investigation. Parties shall file written testimony and supplementary material in connection with their presentation at the conference no later than 4:00 p.m. on March 4, 2025. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures*, available on the Commission's website at https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf, elaborates upon the Commission's procedures with respect to filings.