UNITED STATES INTERNATIONAL TRADE COMMISSION Washington, D.C.

In the Matter of

CERTAIN REDUCED FOLATE NUTRACEUTICAL PRODUCTS AND L-METHYLFOLATE RAW INGREDIENTS USED THEREIN

Inv. No. 337-TA-857

NOTICE OF INSTITUTION OF INVESTIGATION

Institution of investigation pursuant to 19 U.S.C. § 1337

AGENCY: U.S. International Trade Commission

ACTION: Notice

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on September 10, 2012, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, on behalf of South Alabama Medical Science Foundation of Mobile, Alabama; Merck & Cie of Switzerland; and Pamlab LLC of Covington, Louisiana. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain reduced folate nutraceutical products and l-methylfolate raw ingredients used therein by reason of infringement of certain claims of U.S. Patent No. 5,997,915 ("the '915 patent"); U.S. Patent No. 6,673,381 ("the '381 patent"); U.S. Patent No. 7,172,778 ("the '778 patent"); and U.S. Patent No. 6,011,040 ("the '040 patent"). The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainants request that the Commission institute an investigation and, after the investigation, issue an exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Room 112, Washington, D.C. 20436, telephone (202) 205-2000. Hearing impaired individuals are advised that information on this matter can be obtained 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 at http://www.usitc.gov. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at http://edis.usitc.gov.

FOR FURTHER INFORMATION CONTACT: The Office of the Secretary, Docket Services Division, U.S. International Trade Commission, telephone (202) 205-1802.

AUTHORITY: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.10 (2012).

SCOPE OF INVESTIGATION: Having considered the complaint, the U.S. International Trade Commission, on October 10, 2012, ORDERED THAT –

- (1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain reduced folate nutraceutical products and I-methylfolate raw ingredients used therein that infringe one or more of claims 37, 39, 40, 47, 66, 67, 73, 76, 78-81, 83, 84, 86-89, 91, 92, 94-97, 99, 100, 110, 111, 113, 117, and 121 of the '915 patent; claims 22, 26, and 32-38 of the '381 patent; claims 1, 4-6, and 15 of the '778 patent; and claims 1-3, 5, 6, 8, 9, 11-15, and 19-22 of the '040 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;
- (2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:
 - (a) The complainants are:

South Alabama Medical Science Foundation 307 University Boulevard PO Box U-1060 Mobile, AL 36688

Merck & Cie Weisshausmatte 6460 Altdorf Switzerland

Pamlab LLC 4099 Highway 190 Covington, LA 70433

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Gnosis SpA Via Lavoratori Autobianchi 1 20832 Desio (MB) Italy Gnosis Bioresearch SA Via Lischedi, 4 6592 Sant'Antonino Switzerland

Gnosis USA Inc. 160 North Main Street Doylestown, PA 18901

Macoven Pharmaceuticals LLC 33219 Forest West Street Magnolia, TX 77354

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not participate as a party in this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.13. Pursuant to 19 C.F.R. §§ 201.16(d)-(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Lisa R. Barton

Acting Secretary to the Commission

Issued: October 10, 2012