UNITED STATES INTERNATIONAL TRADE COMMISSION Washington, D.C.

In the Matter of

CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("rHSA") AND PRODUCTS CONTAINING SAME

Inv. No. 337-TA-1238

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 December 16, 2020, under section 337 of the Tariff Act of 1930, as amended, on behalf of Ventria Bioscience Inc. of Junction City, Kansas. Supplements to the complaint were filed on December 16, and 22, 2020. The complaint, as supplemented, 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 plant-derived recombinant human serum albumins ("rHSA") and products containing same by reason of infringement of certain claims of U.S. Patent No. 10,618,951 ("the '951 patent"); and U.S. Patent No. 8,609,416 ("the '416 patent"). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute. The complaint also alleges violations of section 337 based on the importation into the United States, or in the sale of, certain plant-derived recombinant human serum albumins ("rHSA") and products containing same by reason of false designation of origin, the threat or effect of which is to destroy or substantially injure an industry in the United States.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a general exclusion order or, in the alternative, a limited exclusion order, and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at https://edis.usitc.gov. For help accessing EDIS, please email EDIS3Help@usitc.gov. 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 https://www.usitc.gov.

FOR FURTHER INFORMATION CONTACT: Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205-2560.

SUPPLEMENTARY INFORMATION:

AUTHORITY: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.10 (2020).

SCOPE OF INVESTIGATION: Having considered the complaint, the U.S. International Trade Commission, on January 14, 2021, ORDERED THAT –

- (1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine:
 - (a) 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 products identified in paragraph (2) by reason of infringement of one or more of claims 1-3 and 11-13 of the '951 patent and claims 1-3, 5-7, 10, 12, 18-20, and 22-25 of the '416 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337; and
 - (b) whether there is a violation of subsection (a)(1)(A) of section 337 in the importation into the United States, or in the sale of, certain products identified in paragraph (2) by reason of false designation of origin.
- (2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is: plant-derived recombinant human serum albumins ("rHSA") and products containing the same, such as lyophilized powders and liquid suspensions primarily containing rHSA along with naturally-occurring plant expression byproducts, such as plant heat shock proteins and/or plant fatty acids, as well as cell culture media supplements formulated with such rHSA products.
- (3) 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 complainant is:

Ventria Bioscience Inc. 2718 Industrial Drive Junction City, Kansas 66441

(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:

Wuhan Healthgen Biotechnology Corp. No. 666 Gaoxin Avenue East Lake High-Tech Development Zone Wuhan, China, 430075

ScienCell Research Laboratories, Inc. 1610 Faraday Avenue Carlsbad, California 92008

Aspira Scientific, Inc. 521 Cottonwood Drive, Suite 112 Milpitas, California 95035

eEnzyme LLC 963 Featherstone Street Gaithersburg, Maryland 20879

- (c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, S.W., Suite 401, Washington, D.C. 20436; and
- (4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

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(e) and 210.13(a), as amended in 85 Fed. Reg. 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainant 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 Secretary to the Commission

Issued: January 15, 2021