UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN RECOMBINANT FACTOR VIII PRODUCTS**	**Inv. No. 337-TA-956**

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 April 16, 2015, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, on behalf of Baxter International Inc. of Deerfield, Illinois; Baxter Healthcare Corporation of Deerfield, Illinois; and Baxter Healthcare SA, of Switzerland. Letters supplementing the complaint were filed on April 21, 2015; May 1, 2015; and May 4, 2015. 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 recombinant factor VIII products by reason of infringement of certain claims of U.S. Patent No. 6,100,061 ("the '061 patent"); U.S. Patent No. 6,936,441 ("the '441 patent"); and U.S. Patent No. 8,084,252 ("the '252 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 a limited 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 Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205-2560.

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 (2015).

SCOPE OF INVESTIGATION: Having considered the complaint, the U.S. International Trade Commission, on May 15, 2015, **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 recombinant factor VIII products by reason of infringement of one or more of claims 19-21, 36, 37, and 39 of the '061 patent; claims 20 and 21 of the '441 patent; claims 1, 5, 8, 10, 14, and 18 of the '252 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to Commission Rule 210.50(b)(1), 19 C.F.R. § 210.50(b)(1), the presiding administrative law judge shall take evidence or other information and hear arguments from the parties and other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. §§ 1337(d)(1), (f)(1), (g)(1)

(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 complainants are:

Baxter International Inc.
One Baxter Parkway
Deerfield, IL 60015-4625

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, IL 60015-4625

Baxter Healthcare SA
Thursgauerstrasse 130
Glattpark (Opfikon)
Switzerland

(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:

Novo Nordisk A/S
Novo Allé
2880 Bagsvaerd
Denmark

Novo Nordisk Inc.
800 Scudders Mill Road
Plainsboro, NJ 08536

(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), 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
Secretary to the Commission

Issued: May 18, 2015