Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: October 8, 2010

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Gaspari Nutrition Inc. Recall

SUGGESTED ACTION: **Unclassified Recall; all Lot Codes of the company's dietary supplement product sold under the name Novedex XT, which was marketed "for increasing natural testosterone production"; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the products being recalled may be distributed in the State of Indiana. The Novedex XT had been sold internationally and domestically, to distributors, wholesalers, retail stores and direct to consumers. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Gaspari Nutrition Nutrition Issues a Voluntary Nationwide Recall of Novedex XT, a Product Marketed as a Dietary Supplement Containing ATD

Company Contact:
Joe Babick Jr.
info@gasparinutrition.com

FOR IMMEDIATE RELEASE – October 7th, 2010 – Lakewood, NJ – Gaspari Nutrition Incorproated, 575 Prospect Street - Suite 230, Lakewood, NJ, announced today that it is conducting a voluntary nationwide recall of all Lot Codes of the company's dietary supplement product sold under the name Novedex XT, which was marketed "for increasing natural

testosterone production" and contains 3,17-keto-etiocholetriene, also known as ATD, an anti-aromatase. Gaspari Nutrition is conducting this consumer level recall after being informed by representatives of the Food and Drug Administration (FDA) that 3,17-keto-etiocholetriene does not meet the definition of a dietary ingredient and therefore the product is in violation of provisions of the Federal Food, Drug, and Cosmetic Act.

Potential adverse events associated with the use of anti-aromatases could include the following: decreased rate of bone maturation and growth, decreased sperm production, infertility, aggressive behavior, adrenal insufficiency, kidney failure, and liver dysfunction. Consumers with liver, kidney, adrenal, or prostate abnormalities are at higher risk for developing adverse events. Gaspari has received no serious adverse events in over five years of marketing Novadex XT.

Novedex XT had been sold internationally and domestically, to distributors, wholesalers, retail stores and direct to consumers, but was discontinued by Gaspari Nutrition for domestic sales on October 4th 2010. The product was sold in blue bottles with a black cap, containing sixty (60) capsules.

Consumers who have Novedex XT in their possession should stop using it immediately. If consumers experience any adverse side effects due to consumption of this product, they should immediately contact a physician. Adverse reactions or quality problems experienced with the use of this product may be reported to Gaspari Nutrition and to the FDA's MedWatch Adverse Event Reporting program online, by regular mail, or by fax:

- Online: www.fda.gov/MedWatch/report.htm <http://www.fda.gov/MedWatch/report.htm[9]>
- Regular Mail: use postage-paid, preaddressed Form FDA 3500 available at www.fda.gov/MedWatch/getforms.htm <http://www.fda.gov/MedWatch/getforms.htm[10]>
- Fax: 1-800-FDA-0178.

The Company is advising consumers who have Novedex XT to return any unused portion to the retail location from which it was purchased or if purchased directly from Gaspari Nutrition to return any unused portion to: Gaspari Nutrition Incorporated, 575 Prospect Street - Suite 230, Lakewood, NJ 08701; Attention: Novedex XT Recall. Consumers with questions regarding this recall can contact the company at 1-732-364-3777 Monday through Friday 9 AM to 5 PM, PST. Consumers who have purchased this product and have medical concerns should consult with their health care providers.

This recall is being conducted in cooperation with the U.S. Food and Drug Administration (FDA).

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