

**SECRETARY OF HEALTH AND HUMAN SERVICES
UNITED STATES OF AMERICA**

NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r) (6) 3495 00 MAR 16 A7:07

To: Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
200 C St. SW., Washington, DC 20204

Date: January 3 1,200 I

Re: This Notice covers the following Brand(s): **Lipo Spa™**.

PLEASE TAKE NOTICE under 21 U.S.C. 403(r) (6):

(i) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement(s): the Goen Group, 8 Ridgedale Avenue, Cedar Knolls, New Jersey 07927 (includes Goen Technologies, Inc., Nutramerica Corporation and Vitamerica Corporation).

(ii) The text of the statement that is being made: see attached Exhibit A.

(iii) The name of the dietary ingredient or supplement that is the subject of the statement: see attached Exhibit A.


(iv) The name of the dietary supplement (including brand name), if not provided in response to paragraph (a)(2)(iii) on whose label, or in whose labeling, the statement appears: see attached Exhibit A.

CERTIFICATION

The undersigned, being duly authorized by the firm submitting the above Notice of Statements under 21 U.S.C. 403 (r) (6) certifies, as of the date first written above: (a) that the information contained in the Notice is complete and accurate, and (b) that the notifying firm has substantiation that the Statement(s) to which this Notice applies is truthful and not misleading.

The undersigned certifies that the above Certification is true and is aware that the undersigned is subject to punishment as for perjury if the Certification is willfully false. This Certification is made under 18 USC 100 1 which makes it a crime to submit false information to the Government.

Prepared by:
Ralph Fucetola, JD
Corporate Attorney 975 0162


Albert M. Fleischner, Ph.D.(Pharm.)
Chief Operating Officer

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NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)

Exhibit A

1. Brand Name(s) Included herein: **Lipo Spa**

2. Dietary Ingredients or Supplements Included herein: Chitosan

3. Statements Made with regard to the Ingredient:
 - a. Chitosan soaks up to 4 to 5 times its weight in fat.

 - b. Chitosan ingestion has been shown to cause the excretion of 5 to 10 times more fat than any other natural fiber tested including kapok, pectin, guar, cellulose, acacia, **chitin**, carrageen, sodium alginate, locust bean, konjac (glucomannan), karaya, furcellaran and agar.

 - c. Chitosan is a non-digestible dietary fiber that binds fats and increases the excretion of dietary fats and cholesterol.

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