



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

7898 01 JUN 11 P2 04

MAY 14 2001

Ms. Shirley L. Gerard
Vice President, CEO
Gempro International, Inc.
415 S Camp Meade Road
Suite 127
Linthicum, Maryland 21090

Dear Ms. Gerard:

This is in response to your letters of April 23, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Gempro International, Inc., is making the following claims, among others, for the products below:

Joint+

"...for joint discomfort..."

SmartBerry™

"...cancer, heart disease, and other ailments."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

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Please contact us if we may be of further assistance.

Sincerely,

for Robert J. Moore

John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Baltimore District Office, Office of Compliance, HFR-MA240

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:afp:5/4/01:docname:75650.disc03



4 Letter
78650

April 23, 2001

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

**NOTIFICATION OF STATEMENTS
OF NUTRITIONAL SUPPORT**

This notification is filed pursuant to section 403 (r) (6) of the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. Section 343(r)(6).

Name of dietary supplement

Joint +

Statements of nutritional support

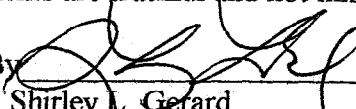
With Glucosamine HCl and
Chondroitin SUL plus
Vitamins A, C, E, B6 and selenium

Will improve and help maintain
the health of strengthening joints,
ligaments, and tendons

Clinical studies have shown the
combination glucosamine and
chondroitin to one of most
effective supplements for joint
discomfort.

I certify that the information contained in this notice is complete and accurate,
and that we have substantiation that the statements are truthful and not misleading.

By


Shirley L. Gerard
Vice President, CEO



April 24, 2001

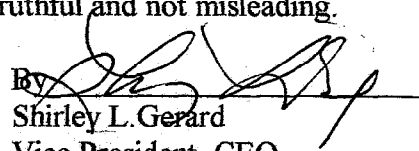
Office of Special Nutritionals (HFS-450)
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Washington, DC 20204

**NOTIFICATION OF STATEMENTS
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This notification is filed pursuant to section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act (FDC Act), 21 U.S.C. Section 343 (r) (6).

Name of Dietary Supplement	SmartBerry™
Statements of nutritional support	Primary ingredient is blueberries and Acetyl-L-cartine Blueberries are recognized for their high antioxidant activity which may be possible to prevent aging, cancer, heart disease, and other ailments. Studies show their is a potential to help the short-term memory lost, mobility (Jean Mayer USDA Human Nutrition Research Center on Aging Acetyl-L-Cartine helps the conversion of choline into acetylcholine , a key neurotransmitter in the body.

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statements are truthful and not misleading.

By 
Shirley L. Gerard
Vice President, CEO