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Patricia Siuta-Cruce, Ph.D.
Vice President, Technology
Balchem Corporation
P.O. Box 175
Slate Hill, New York 10973

Dear Dr. Siuta-Cruce:

This is in response to your letter of November 20, 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 Balchem Corporation is making the following claim, among others, for its product **Vitashure®**: "May help to reduce plasma homocysteine, a known cardiovascular risk factor."

This statement is a statement about the relationship between choline and the risk of cardiovascular disease and is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B). FDA has not authorized a health claim on the relationship choline and the risk of cardiovascular. A dietary supplement that bears an unauthorized health claim is a misbrand dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, this claim subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to prevent a disease, namely, cardiovascular disease.

Your submission also states that you are making the claim "may help to reduce fatty deposits in the liver and liver damage" for the product **Vitashure®**.

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 statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate liver diseases. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is 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.

975-0163

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Please contact us if you require further assistance.

Sincerely,



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, New York District Compliance, HFR-NE140

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-810 (Foret)

HFS-811 (file)

HFD-310

HFD-314 (Aronson)

HFS-607

HFV-228 (Benz)

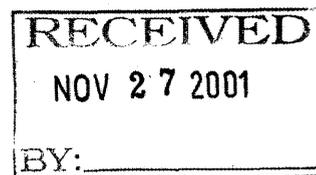
GCF-1 (Nickerson)

f/t:HFS-811:rjm:11/27/01:docname:cruce.adv:disc62

B A L C H E M C O R P O R A T I O N

PATRICIA SIUTA-CRUCE, Ph.D.
VICE PRESIDENT, TECHNOLOGY

November 20, 2001



Dr. Robert Moore
Office of Nutritional Products, Labeling and Dietary Supplements
Room 1848
Food and Drug Administration
200 C Street
Washington, DC 20204
Tel: (202) 205-4561

Re: Notification of Structure/Function Claims for a Dietary Supplement

Dear Dr. Moore:

Pursuant to Section 403§(6) of the Federal Food, Drug, and Cosmetic Act and to 21 CFR 101.93, Balchem Corporation hereby notifies the Food and Drug Administration that it has included the following statement on the label and/or in the labeling of a dietary ingredient that Balchem manufactures and markets as a bulk material for inclusion in dietary supplement products manufactured by Balchem's customers.

The following required information is hereby provided.

- 1) Name of the manufacture, packer, or distributor of the dietary supplement that bears the statement.

Balchem Corporation (manufacturer)

- 2) The text of the statement(s) that is(are) being made.

- 1) *May help to reduce fatigue and increase vigor during strenuous exercise*
- 2) *May benefit mild memory problems associated with aging*
- 3) *May help to reduce plasma homocysteine, a known cardiovascular risk factor*
- 4) *May help to reduce fatty deposits in the liver and liver damage*
- 5) *Choline supplementation during pregnancy may lead to a lifelong improvement of visuospatial memory in children born of the pregnancy*
- 6) *Choline supplementation during infancy and childhood may help to improve lifelong memory*

- 3) The name of the dietary ingredient or supplement that is the subject of the statement.

Name of dietary ingredient: *Choline*

- 4) The name of the dietary supplement (including brand name), if not provided in response to paragraph (a)(2)(111) on whose label, or in whose labeling, the statement appears.

Name on label: *Choline bitartrate, Choline Chloride, or
Choline Dihydrogen Citrate*

Brand name: *Vitashure®*

- 5) Signature of person who can certify the accuracy of information presented and contained in this notice, pursuant to 21 CFR 101.93.(a)(3)

I certify that the information contained in this notice is complete and accurate, and that Balchem Corporation has substantiation that the statement is truthful and not misleading.

Patricia Siuta-Cruce 11/20/01
Patricia Siuta-Cruce, Ph.D.
V.P., Technology
Balchem Corporation

Thank you in advance for your attention to this notice.

Sincerely,

Patricia Siuta-Cruce 11/20/01
Patricia Siuta-Cruce, Ph.D.