DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Public Health Service

Memorandum

MAY - 4 1999

Date

From Senior Regulatory Scientist, Regulatory Branch, Division of Programs & Enforcement Policy (DPEP), Office of Special Nutritionals, HFS-456

'99 MAY 10 A9:40

Subject 75-day Premarket Notification for New Dietary Ingredient

To Dockets Management Branch, HFA-305

New Dietary Ingredient:	acamprosate (acetyl-homotaurine)
Firm:	Chemtech Pharmics, Inc.
Date Received by FDA:	March 11, 1999
90-day Date:	June 8, 1999

In accordance with the requirements of section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification for the aforementioned new dietary ingredient should be placed on public display in docket number 95S-0316 after June 8, 1999.

Robert J. Moore, Ph.D.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

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Mr. Isaac Bulka
Chemtech Pharmics, Inc.
50 Hempstead Gardens Drive
West Hempstead, New York 11552

Dear Dr. Bulka:

This letter is in response to your submission of a notification to the Food and Drug Administration (FDA) received on March 11, 1999 for a new dietary ingredient pursuant to 21 U.S.C. 350b(a)(2). Your letter notified FDA of your intent to market a product containing acetyl-homotaurine, also known as acamprosate.

The term "dietary supplement" is defined in the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Dietary Supplement Health and Education Act of 1994 (the DSHEA), as a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients (21 U.S.C. 321(ff)(1)). The dietary supplement definition also states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(i) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the diet, and are labeled as a dietary supplement (21 U.S.C. 321(ff)(2))).

The definition excludes an article that is approved as a new drug under section 505 of the Act or an article authorized for investigation as a new drug, for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval or authorization, marketed as a dietary supplement or as a food (21 U.S.C. 321(ff)(3)(B)).

Acamprosate is the subject of substantial clinical studies being conducted in the United States to determine if it is a safe and effective drug treatment for alcohol dependence. The existence of these substantial clinical studies has been made public[1,2]. Therefore, acetyl-homotaurine, or acamprosate, is excluded from being a dietary supplement under 21 U.S.C. 321(ff)(3)(B).

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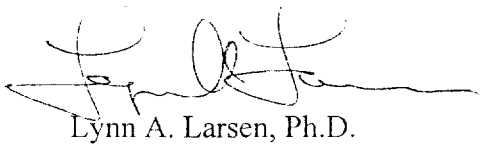
[1]Anthenelli, R. Acamprosate: A Possible New Medication for the Treatment of Alcohol Dependence. OAADAC Newsletter, Volume X, Issue XIII, pp. 1-2, Cincinnati Chapter of Ohio Association of Alcoholism & Drug Abuse Counselors, December 1997.

[2]Morrow, D.J. Curbing the Urge to Drink. Drug to Treat Alcoholism Sets Off Controversy in U.S. New York Times, Friday, July 31, 1998.

A product containing acetyl-homotaurine that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease or is intended to affect the structure or function of the body is a drug as described in 21 U.S.C. 321(g)(1). Such a product is also a new drug, as defined in 21 U.S.C. 321(p). which requires FDA approval under 21 U.S.C. 355(a) prior to marketing. The marketing of new drugs without an approved new drug application is prohibited under 21 U.S.C. 331(d).

Please contact us if you have any questions concerning this matter.

Sincerely,



Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Chemtech Pharmics, Inc.

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50 Hempstead Gardens Drive
West Hempstead, NY 11552

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Office of Special Nutritionals
200 C Street SW
Washington DC, 20204

To Whom It May Concern,

Pursuant to the Dietary Supplement and Health Education Act, please find enclosed data affirming the short and long term safety of a new dietary supplement [acetyl-homo taurine], for the mandatory 75 day pre-market notification.
We are making no claims of efficacy whatsoever. However, the safety data for doses as high as 2000 mg per day is found herein. It is our intention to market this product in a dose substantially lower.

We appreciate the time and effort that the FDA may take in dealing with this subject. Please feel free to communicate any thoughts and/or concerns regarding the above.

Sincerely,

Dr. Isaac Bulka