



APR - 6 2004

Mr. Gary Wong Kwan Po  
Assistant Sales Manager  
Unit 714 7/F  
Miramar Tower  
1-23 Kimberly Road  
Tsimishatsui, Kowloon  
Hong Kong SAR

Dear Mr. Po:

This is to inform you that the notification, dated January 20, 2004, that you submitted pursuant to 21 U.S.C. 350b(a)(2) (section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on January 29, 2004. Your notification concerns the substance "2-aminoethanethiol hydrochloride," also known as cysteamine hydrochloride (HCl) that you intend to market as a new dietary ingredient under the product name, "S-BI II."

According to the notification, you intend to sell 300 milligram (mg) capsules containing 81 mg of cysteamine HCl. You describe the other major ingredients in each capsule as Alanine (25.00 mg), Glycine (22.00mg), Serine (3.00 mg), Arginine (0.10 mg), Throsine (0.50 mg), and Threonine (0.30 mg). You state that the other ingredients in your product are starch (88.50 mg) and Avicel (79.60 mg). Under the conditions of use stated in the labeling of your product you indicate that the suggested dosage is "3-4 capsules each, 2 times daily in the morning and at night." Under precautions you state "Keep out of reach of children. Store in cool, dry place, tightly closed. Protect from light. This product contains a dessicant for maximum potency and freshness."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be

adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

It is unclear on what basis you assert that "2-aminoethanethiol hydrochloride (cysteamine HCL)" that is the subject of your notification is a "dietary ingredient" within the meaning of 21 U.S.C. 321(ff)(1) that may be lawfully used in dietary supplements. A dietary supplement means, among other things, a "product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

- (A) a vitamin;
- (B) a mineral;
- (C) an herb or other botanical;
- (D) an amino acid;
- (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)."

FDA requests that you submit information explaining your basis for asserting that 2-aminoethanethiol hydrochloride falls under the definition of dietary ingredient in 21 U.S.C. 321(ff)(1).

In addition, your notification presents a novel issue for FDA to consider with respect to whether the product includes an article that has been approved as a new drug under 21 U.S.C. 355 (21 U.S.C.321(ff)(3)(B)(i)). FDA intends to complete its evaluation shortly and send you a response to your notification explaining FDA's decision about whether your products are dietary supplements within the meaning of 21 U.S.C. 321(ff).

This letter is to alert you within the 75-day notification period that FDA has concerns about whether your product can lawfully be marketed as a dietary supplement. Please note that failure to respond to a notification within the 75-day timeframe does not constitute a finding by the agency that the ingredient or a product that contains the ingredient is safe or is not adulterated under 21 U.S.C. 342. 21 C.F.R.190.6(f).

If you have any questions or would like to arrange a meeting concerning this matter, please contact Victoria Lutwak at (301) 436-2375.

Sincerely yours,



*for* Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

cc:

Reviewed

R/D:GChang:03/04/04;edited LP 4/05/04

HFS-810: Pellicore:

HFS-810: Moore

HFS-810: Walker

HFS-810: Lutwak

F/T-HFS-810:4/06/04gchang

Reviewed:

I. Chan OCC Drafted

G. Overholser OCC

cc:

HFA-224 (yellow box copy)

HFS-605 (Field Programs)

HFS-810 (GChang- 4 paper copies)

NDI 276-(S-BI II)

CTS 87113

NDI 276 IAL 040406 (Cysteamine HCL-S-BI II)