DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: MAR 03 2004

From: Consumer Safety Officer, Division of Dietary Supplement Programs, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: Piracetam

Firm/Person: David Tolson

Date Received by FDA: October 27, 2003

90-Day Date: 1/25/04

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Gloria Chang 03/01/04

95S-0316

RPT 215

DEPARTMENT OF HEALTH AND HUMAN SERVICE Public Health Service

Food and Drug Administration
College Park, MD 20740

JAN - 9 2004

Mr. David Tolson
1420 Turk Street # 1208
San Francisco, California 94115

Dear Mr. Tolson:

This is to inform you that the notification 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 October 27, 2003. Your notification concerns the substance "Piracetam" also known as 2-oxo-pyrrolidone or 2-oxo-1-pyrrolidine acetamide, that you intend to market as a new dietary ingredient.

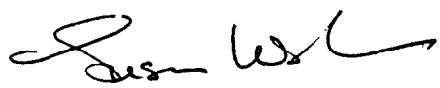
The notification states that the product will contain Piracetam only and that the suggested dosage will be 2.4 -4.8 grams (g) daily. You state that your product will not have specific conditions for use and that consultation with a physician will be recommended if any medical condition is present.

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.

FDA has carefully considered the information in your submission, and the agency has concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing Piracetam will reasonably be expected to be safe.

If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-2375.

Sincerely yours,



Susan J. Walker, M.D.
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