

**MAY 19 2006**

David H. Bechtel, PhD., DABT
CANTOX U.S. Inc.
1011 U.S. Highway 22, Suite 200
Bridgewater, New Jersey 08807

Dear Dr. Bechtel:

This is to inform you that the notification, dated March 2, 2006, 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)) on behalf of your client, Yung Zip Chemical Ind. Co., Ltd was filed by the Food and Drug Administration (FDA) on March 7, 2006. Your notification concerned the substance that you identified as "Elite Curcumin". According to your notification, "Elite Curcumin" is synthesized and is not derived from *Curcuma Longa L.*

According to your notification "The dietary supplement containing the Elite Curcumin dietary ingredient will be in capsule, tablet granule and powder form. The curcumin capsules/tablets/sachet will be clearly labeled and promoted as a dietary supplement. A description of the number of capsules/tablets/sachet per serving size will appear on the label. Consumption of up to 1500 mg per day will be suggested or recommended in the label directions..."

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 21 U.S.C. 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.

Based on the information in your submission, FDA was unable to determine the identity of your new dietary ingredient, "Elite Curcumin". For example, the description of the synthesis of your proposed new dietary ingredient was inadequate to permit the FDA to identify your

specific new dietary ingredient. In addition, your notification cites "USP 27" and "the Merck Index" as the sources of methods used for the analysis of "Elite Curcumin". The specific methods were not identified or described in your notification and it is unclear to FDA which methods were used or how these methods established the identity of your proposed new dietary ingredient. Methods from a private laboratory were identified by a code name but were not further described. It is unclear to FDA how methods for which no description was provided could be used to establish the identity of the ingredient that you describe variously as "Elite Curcumin", "Yung Zip Chemical Ind. Co., Ltd. Elite Curcumin", and "a synthetically produced nature-identical curcumin product".

Since FDA could not determine the identity of your new dietary ingredient, it is not readily apparent whether the substance 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. The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 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)."

Your notification contains history of use and other information for turmeric, turmeric oleoresin and other extracts of *Curcuma longa* L. It is unclear how these botanically-derived materials are qualitatively and quantitatively similar to the synthetically-derived "Elite Curcumin" that is the subject for your notification.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "Elite Curcumin", when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of March 7, 2006. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter please contact Linda Pellicore, Ph.D. at (301) 436-2375.

Sincerely yours,

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