



Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

OCT 13 2006

Hong Liao, President
TJ Panorama, Inc.
P.O. Box 584
Fairfield, Connecticut 06824

Dear Mr. Liao:

This is to inform you that the notification, dated July 27, 2006, you submitted pursuant to 21 U.S.C. 3501b(a)(2) (section 413 of the Federal Food, Drug, and Cosmetic Act (the Act)) was received by the Food and Drug Administration (FDA) on August 1, 2006. Your notification concerns the new dietary ingredients AMP, CMP, GMP, UMP, and RNA, that you intend to market as a dietary supplement product called "Nucleic Acid Supplement Capsules".

According to your notice the conditions for use for the ribonucleotides contained in "Nucleic Acid Supplement Capsules" are to take "2 capsules per time with water, twice daily. Children 1 capsule daily. Caution: not suitable for people suffering from gout."

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.

Your notification concerning "Nucleic Acid Supplement Capsules" does not comply with the requirements of 21 CFR 190.6 and is incomplete. Your notice does not provide information on the history of use or other safety information for your new dietary ingredients or your dietary supplement containing the new dietary ingredients. The notification contains some history of use and other information on studies involving ribonucleic acids but not on the other components of your notification.

FDA is unable to determine whether the information cited in your notice provide an adequate basis for a conclusion that the dietary supplement will reasonably be expected to be safe because the information contained in your notice is incomplete. If you market your product without submitting a notification that meets the requirements of 21 CFR 190.6 (<http://www.cfsan.fda.gov/~lrd/cfr190-6.html>), or market your product less than 75 days after submitting such a notification, your product is considered adulterated under 21 V.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 V.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of August 1, 2006. After the 90-day date, the notification will be placed on public display at FDA's Division of Docket Management 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 Theresa Prigmore at (301) 436-1446.

Sincerely yours,



Linda S. Pellicore, Ph.D.
Supervisory Team Leader, Senior Toxicologist
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety and Applied Nutrition