

**Memorandum**

Date:           MAY 25 2006          

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: AMP, CMP, GMP, UMP, RNA

Firm: TJ Panorama, Inc.

Date Received by FDA: 2/27/2006

90-Day Date: 5/28/2006

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.

          Victoria Lutwak          

19955-0316

RPT340



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

MAY 10 2006

Dear Mr. Liao:

This is to inform you that the notification, dated February 18, 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 February 27, 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. The following items were not included with your submission: (1) An original and two copies of the notification, and (2) an adequate description of the dietary supplement that contains your new dietary ingredients.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "Nucleic Acid Supplement Capsules," 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 February 27, 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 Linda Pellicore, Ph.D. 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

TJ Panorama Inc  
P.O box 584, Fairfield, CT06824 www.tjpanorama.com  
Tel(203)2595876 Fax (203)2595876 Email hliao@tjpanorama.com

February 18, 2006

Division of Standards and Labeling Regulations  
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD, 20740-3835  
Telephone Number: (301) 436-2371

FEB 27 2006

Dear Sir or Madam,

TJ Panorama Inc is intent to market the Nucleic Acid Supplement product in US. From attached paper, you could find the pre-marketing Notification for this. Please review it.

AIMS #  
2006-1526  
DDSP # 1601

Sincerely,

Hong Liao  
President



TJ Panorama Inc  
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Tel(203)2595876 Fax (203)2595876 Email hliao@tjpanorama.com

1. The name and complete address of distributor of a dietary supplement that contains the new dietary ingredient, or of the new dietary ingredient;

TJ Panorama Inc.

P.O box 584, Fairfield, CT06824 www.tjpanorama.com

2. The name of the new dietary ingredient that is the subject of the premarket notification, including the Latin binomial name (including the author) of any herb or other botanical;

No	Name
1	Adenosine 5' monophosphatefree acid (AMP)
2	Cytidine 5' monophosphate free acid (CMP)
3	Guanosine5' monophosphate disodium salt (GMP)
4	Uridine5' monophosphate disodium salt (UMP)
5	Ribonucleic acid(RNA)

- a). A description of the dietary supplement or dietary supplements that will contain the new dietary ingredient including:

TJ Panorama Inc  
 P.O box 584, Fairfield, CT06824 www.tjpanorama.com  
 Tel(203)2595876 Fax (203)2595876 Email hliao@tjpanorama.com

Nucleic Acid Supplement Capsules is made of the above dietary ingredients.

b).the level of the new dietary ingredient in the dietary supplement;

No	Name	Level of new ingredients
1	Adenosine 5' monophosphatefree acid (AMP)	—
2	Cytidine 5' monophosphate free acid (CMP)	—
3	Guanosine5' monophosphate disodium salt (GMP)	—
4	Uridine5' monophosphate disodium salt (UMP)	—
5	Ribonucleic acid(RNA)	—

<b>SUPPLEMENT FACTS</b>	
Serving size 2 capsules	(700mg)
Amount per serving	
Calories 2	
Calories from Fat 0	
Nucleic Acids	480mg*
Total Fat	0
Protein	<1g
*Daily Value not established	

**OTHER INGREDIENTS:** gelatin, water

b. The conditions of use recommended or suggested in the labeling of the dietary supplement, or if no conditions of use are recommended or suggested in the labeling of the dietary supplement, the ordinary conditions of use of the supplement;

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**SUGGESTED USE:** 2 capsules per time with water, twice daily. Children 1 capsule daily.

**CAUTION:** not suitable for people suffering gout.  
Storage in a cool, dry place at room temperature, tightly closed.

3. The history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe, including any citation to published articles or other evidence that is the basis on which you have concluded that the new dietary supplement will reasonably be expected to be safe. You must submit reprints or photostatic copies of published information that you reference in support of the notification material. You must submit an accurate and complete English translation of any material you submit in a foreign language

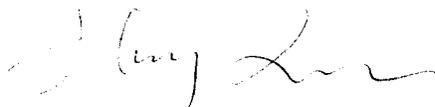
The Nucleic Acid Supplement is manufactured by Zhen-Ao group in China. The nucleic acid supplement has been in the Chinese market since 1996. It has been marketed across over the mainland of China with 33 sales facility, more than 300 sales agents and over 2000 franchise houses. The Nucleic Acid Supplement Capsules is the major food supplement product accepted in Chinese community worldwide.

#### Appendix

1. Letter of authorization
2. Original Manufacture and product Profile
3. Clinical Tests Reports

Hong Liao

President



TJ Panorama Inc.



## Letter of Authorization

We, Zhen-Ao Group Co., Ltd, hereby authorize T.J. Panorama Inc to be the exclusive distributor of ZHEN-AO Nucleic Acid Supplement Product within the valid period of this letter of authorization in United States market. (there is no restriction to marketing quantity in this period) .

During this period, all legal responsibilities and obligations relating to marketing the said product will be solely taken by T.J. Panorama Inc. And, all legal responsibilities and obligations relating to quality of the said product will be taken by Zhen-Ao Group Co., Ltd.

In 30 days before the expiration of this letter of authorization, Zhen-Ao Group Co., Ltd will, according to the marketing performance, provide T.J. Panorama Inc with priority to renew this letter of authorization or sign a long-term marketing agreement with Zhen-Ao Group Co., Ltd.

This letter of authorization will have the validity from Jan 31<sup>st</sup> , 2006 to Dec 31<sup>st</sup>, 2006.

Board chairman: Chen Yusong

Signature:

ZHEN-AO Group Co., Ltd.

Registration Number: 2102002115317