



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

0020 E SF-5 P2:22

AUG - 9 2006

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

Dear Mr. Liao:

This is in response to your letter dated July 27, 2006 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter states that you intend to make the following claims, among others, for the products **CellRejuvenate**, **Zhen-Ao** and **GeneNutrient**:

“Shortens recovery time from illness”
“Enhances the capacity to heal naturally.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6)¹. These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

¹In the preamble to the final rule on structure function claims published in the January 6, 2000 Federal Register (65 FR 1000 at 1028-9; section Q) FDA discussed the types of immune system claims that may be disease claims under the Act. A copy of the rule can be found at <http://www.cfsan.fda.gov/~lrd/fr000106.html>.

97S 0163 LET 895

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Please contact us if we may be of further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

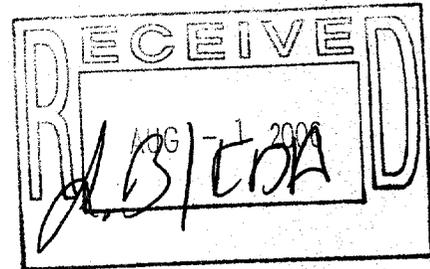
Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, New England District Office, Office of Compliance, HFR-NE240

TJ Panorama Inc
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July 27, 2006

Susan J. Walker M.D.
Division of Dietary Supplement Programs
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



Dear Dr. Susan J. Walker,

Thanks for your letter on May 10 2006 and the opportunity to have conference call with your team on May 22, 2006 to discuss our Pre-marketing Notification Application that TJ Panorama Inc is intent to market the Nucleic Acid Supplement product in US.

In order to meet the guideline of 21 U.S.C. 343 (r) (6) which requires that manufacturers of dietary supplements that make structure/function claims on labels or in labeling must submit a notification to FDA no later than 30 days after marketing the dietary supplement that includes the text of the structure/function claims.

This notification is to inform that the label for this product will carry the following claim.

This product label intends to claim the following items

- Promotes healthy immune systems
- Shortens recovery time from illness
- Enhances the capacity to heal naturally

This product label also includes the disclaimer as following

These statements have not been evaluated by Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

This label may be marketed under the trademark or brand as following

- CellRejuvenate
- Zhen-Ao

2006-6386

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- GeneNutrient

Contains all natural ingredients
No artificial colors
No artificial flavors
Free of preservatives
Keep out of reach of children

A paper bag enclosed in the bottle is for moisture extraction only. Do not ingest.

Exp. Date:



保健食品
ZHEN-AO GROUP
www.zhen-ao.com

CellRejuvenate

NUCLEIC ACID SUPPLEMENT

- Promotes healthy immune system
- Shortens recovery time from illness
- Enhances natural cure capacity

60 CAPSULES, 350MG EACH

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

SUPPLEMENT FACTS	
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
SUGGESTED USE: 2 capsules take with water, twice a day. Children 1 capsule daily.
CAUTION: not suitable for people suffering from gout. Store in a cool, dry place at room temperature, tightly closed.


Manufactured by: Zhen-ao group co.,Ltd. Dalian, P.R. China 116620
Distributed by: TJ panorama Inc P.O.Box 584, Fairfield CT 06824
Tel:0086-411-87406633
www.zhen-ao.com www.cellrejuvenate.com

Please reference "Nucleic Acid Supplement" Pre-marketing Notification application for product ingredient and safety information

The utility of nucleic acid as a supplement is not new to the nutrient consumer market. Since the 1950s, New York physician Benjamin Frank, M.D practiced his theory through the use of nucleic acids in the therapy of aging and chronic degenerative diseases. Dr. Frank reported the results of his research and clinical experience in the following books published during this time.

1. Frank, B. Nucleic Acid Therapy in Aging and Degenerative Disease-A Metabolic Approach with DNA, RNA and Related Metabolites. Psychological Library, New York, 1968.
2. Frank, B. Dr. Franks No Aging Diet. The Dial Press, New York, 1976.
3. Frank, B. Nucleic Acid and Anti Oxidant Therapy of Aging and Degeneration, Royal Health Books, Ltd., Long Island, NY, 1977.

Dr. Frank and other Medical professions found that RNA had a number of profound effects:

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- 1) Improve general health and retard aging (including reduced skin wrinkling and increased skin elasticity)
- 2) Energizing
- 3) Help to repair damage caused by disease and strengthens victims for the torment they must face in returning to normal life
- 4) Anti-low temperature and freezing
- 5) Permit the body to perform better with less oxygen
- 6) Cognitive enhancing.

Zhen-AO group in China underwent human body clinical research on this product (Nucleic Acid supplement). The following are the results cited from the published paper

- 1). Enhanced the antioxidant function in human body
 - 2). Improved the cellular and fluid immune function among old people
 - 3). Delayed the aging process
 - 4). Improved anti-fatigue effect of human body
 - 5). Repaired damaged genes.
-
1. The Effect of Zhen-Ao product on the human body (Zhen-Ao nucleic acid capsule, Zhishuping capsule, Gantai capsule) summary for project, Academy of Public Hygiene, Funda University of Basic Science, Tongji University. March, 2003
 2. Assay of regulatory effect of Zhen-Ao nucleic acid capsule on human immune function by oral administration, Academy of Public Hygiene, Fundan University, Jan 21, 2003
 3. A study on the role of nucleic acid capsule on delay-aging function in rates and drosophila, Dai Quiping, Zhang Xinwen, etc., Journal of Tongji University (Medical Science), Vol. 24, No.1, Feb 2002
 4. Food Test of Anti-fatigue Effort of Zhen-Ao nucleic Acid in human, Department of Nutrition and Food Hygiene Academy of Public Hygiene Fudan University, March 10, 2003
 5. Clinical Observation on Zhen-Ao Nucleic Acid in Treatment of Cerebrovascular Diseases, Journal of Shenyang Medical College, Vol. 1, No.3, Sept 1999
 6. Study on Resistant Aging of Nucleic Acid, Yang Wenxiu, Li Shu, ect. Journal of Shenyang Medical College, Vol.2 No.4, Dec. 2000
 7. Effect of Nucleic Acid on the Sex Hormone in Old Man, Yang Wenxiu, Li Shu, ect. Journal of Shenyang Medical College, Vol.3 No.1, Dec. 2001
 8. The Healing Observation of Chronic Hepatic Disease with Zhen-Ao Gantai Capsule, Ge Daru, China Chngkuang Yixue, Vol. 16 No.1, Feb, 2003.

The results passed the appraisal of expert groups in Beijing April 14, 2003. Which is the first clinical research on healthcare products in China.

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As the attached research concluded that ZHEN-AO Nucleic Acid Capsule could enhance the body immunity.

The nucleic acid supplement has been in the Chinese market since 1996. The Nucleic Acid Supplement Capsules is the major food supplement product accepted in Chinese community worldwide based on Zhen-Ao' statistics on 2005.

Country	Number of customers
China	1,050,000
Japan	13,500
South Korea	9,000
Malaysia	28,500
Southeast Asia	4,500

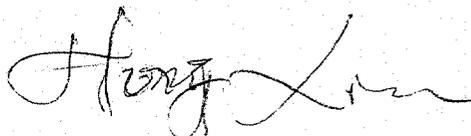
To sum up, Based Dr. Frank and other medical Profession's theory and practice, results of Zhen-Ao Nucleic Acid product clinic test, consumer acceptance for this product in China, the function claims for benefits on promoting the immune system, shortening recovery from illness, enhancing nature cure capacity are reliable and reasonable.

Appendix

1. Letter of authorization from Zhen-Ao to TJ Panorama Inc
2. Original Manufacturer and product Profile
3. Clinical Tests Reports
4. Copies of some page from Dr. Benjamin S. Frank "No-Aging Diet"
5. Copies of some page from Dr. Benjamin S. Frank "Nucleic Acid Therapy in Aging and Degenerative Disease-A Metabolic Approach with DNA, RNA and Related Metabolites"
6. Copies of pages from Dr. Frank's Nucleic Acid Therapy In Aging and Degenerative Disease, ISBN 68-59227, published by Psychological Library Publishers, 1968.

Sincerely,
Thanks for your time and considerations

Hong Liao
President



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