DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

0422 '03 JAN 27 P2:14

Date: January 16, 2003

From: Chemist, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-821

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification:	Eicosapentaenoic acid (EPA) and Docosahexaenoic acid (DHA) [Ginseng Fish Oil]
Firm:	YAT CHAU (USA) Inc.
Date Received by FDA:	July 9, 2002
90-Day Date:	October 8, 2002

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.

Kenneth M. P. Taylor, Ph.D.

Attachments

95S-0316

RPT140

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD

SEP 23 2002

Sherman Ye, Ph.D.
Yat Chau (USA), Inc.
131-37A 41ST Avenue, 1ST Floor
Flushing, New York 11355

Dear Dr. Ye:

This is in response to your submission of a new dietary ingredient notification, dated July 6, 2002, to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 350b (a)(2) and 21 Code of Federal Regulations (CFR) Part 190.6. FDA received your notification on July 10, 2002, of your intent to market the product Ginseng Fish Oil which contains the ingredients eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

In accordance with 21 U.S.C. 350b(a)(2), the manufacturer or distributor of a dietary supplement that contains 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 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 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 deemed 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 submission indicates that you intend to market Ginseng Fish Oil as 1000 mg softgel capsules containing 360 mg EPA and 240 mg DHA per serving of 2 softgels with a suggested use for adults of 2 softgels twice daily. Your submission also contains information that you believe establishes that the new dietary ingredients, EPA and DHA, when used under the condition recommended or suggested in the labeling will reasonably be expected to be safe.

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

state in your submission that "This dietary supplement has been in the United States food market for many years." However, your submission contains no information to support this statement nor that establishes that historical use, if any, is relevant to reaching a conclusion that your product, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. Your submission also contains references to articles published in the scientific literature, however, you did not provide copies of any of these studies as required by 21 CFR 190.6(b)(4). Moreover, your submission contains no explanation as to how the information in the scientific references and other information you submitted provided a basis to conclude that your dietary supplement will reasonably be expected to be safe.

Furthermore, your notification is incomplete because it does not comply with 21 CFR 190.6 (copy enclosed). For example, your notification:

- Does not include an original and two copies of the complete notification [21 CFR 190.6 (a)].
- Does not include the Latin binomial name (stating the author) of the herb or botanical [21 CFR 190.6 (b)(2)].
- Does not include a history of use or other evidence of safety establishing that the dietary ingredients, when used under the conditions recommended or suggested in the labeling will reasonably be expected to be safe.
- Does not include photostatic copies of references cited in the notification. (Please note that if any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation.)

You may also view FDA's web site at http://www.cfsan.fda.gov/~dms/ds-ingrd.html for additional details on new dietary ingredient notification requirements.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that Ginseng Fish Oil, 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. After October 8, 2002, the notification and related correspondence from FDA will be placed on

public display at FDA's Dockets Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information that is in the notification will not be disclosed to the public.

If you have any questions concerning this letter, please contact me at (301) 436-2371.

Sincerely yours,

Felicia B. Satchell

Felicia B. Satchell
Director
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Enclosure

[Code of Federal Regulations]
[Title 21, Volume 3]
[Revised as of April 1, 2001]
From the U.S. Government Printing Office via GPO Access
[**CITE: 21CFR190.6**]

[Page 569-570]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 190--DIETARY SUPPLEMENTS--Table of Contents

Subpart B--New Dietary Ingredient Notification

Sec. 190.**6** Requirement for premarket notification.

(a) At least 75 days before introducing or delivering for introduction into interstate commerce a dietary supplement that contains 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, the manufacturer or distributor of that supplement, or of the new dietary ingredient, shall submit to the 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, information including any citation to published articles that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe. An original and two copies of this notification shall be submitted.

(b) The notification required by paragraph (a) of this section shall include:

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

(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;

(3) A description of the dietary supplement or dietary supplements that contain the new dietary ingredient including:

(i) The level of the new dietary ingredient in the dietary supplement; and

(ii) 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;

(4) 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 the distributor or manufacturer of the dietary supplement that contains the new dietary ingredient has concluded that the new dietary supplement will reasonably be expected to be safe. Any reference to published information offered in support of the notification shall be

[[Page 570]]

accompanied by reprints or photostatic copies of such references. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation; and

(5) The signature of the person designated by the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient.

(c) FDA will acknowledge its receipt of a notification made under section 413 of the Federal Food, Drug, and Cosmetic Act (the act) and will notify the submitter of the date of receipt of such a notification. The date that the agency receives the notification submitted under paragraph (a) of this section is the filing date for the notification. For 75 days after the filing date, the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient shall not introduce, or deliver for introduction, into interstate commerce the dietary supplement that contains the new dietary ingredient.

(d) If the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient, or of the new dietary ingredient, provides additional information in support of the new dietary ingredient notification, the agency will review all submissions pertaining to that notification, including responses made to inquiries from the agency, to determine whether they are substantive and whether they require that the 75-day period be reset. If the agency determines that the new submission is a substantive amendment, FDA will assign a new filing date. FDA will acknowledge receipt of the additional information and, when applicable, notify the manufacturer of the new filing date, which is the date of receipt by FDA of the information that constitutes the substantive amendment.

(e) FDA will not disclose the existence of, or the information contained in, the new dietary ingredient notification for 90 days after the filing date of the notification. After the 90th day, all information in the notification will be placed on public display, except for any information that is trade secret or otherwise confidential commercial information.

(f) Failure of the agency to respond to a notification does not constitute a finding by the agency that the new dietary ingredient or the dietary supplement that contains the new dietary ingredient is safe or is not adulterated under section 402 of the act.

[62 FR 49891, Sept. 23, 1997, as amended at 66 FR 17359, Mar. 30, 2001]

一洲美國藥業集團有限公司
YAT CHAU (USA) INC.

131-37A, 41 AVE., 1FL.
FLUSHING, NEW YORK 11355
U.S.A.

TEL : 1-800-238-3189 OR 1-800-864-1282
FAX : 1-888-332-7888 OR 1-718-886-9519
WEB: www.ycmart.com

July 6, 2002

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

Re: Notification to the Secretary of Health and Human Services pursuant to Section 8(a)(2) of the Dietary Supplement Health and Education Act of October 25, 1994 (21 USC: Federal food, Drug and Cosmetic Act). Marketing dietary ingredients under Supplement Health and Education Act.

To Whom It May Concern:

YAT CHAU (USA) INC. is requesting marketing clearance for its dietary supplement Ginseng Fish Oil. The premarket notification information required by FDA's Office of Special Nutritionals is as follows:

1. Classification name: Ginseng Fish Oil.

2. Classification: Dietary supplements and their ingredients are governed and regulated under the Dietary Supplement Health and Education Act. Pursuant to Section 8 of the Act such dietary supplements must reasonably be expected to be safe. IN CONSIDERATION OF THE PROVISIONS OF THIS NEW LEGISLATION, YAT CHAU (USA) INC desires to export and market Ginseng Fish Oil in USA for use as a dietary supplements. This dietary supplement has been in the US food market for many years. It is reasonably expected to be safe. Please see label of product attached hereto as Attachment 1.

3. Label/Labeling/Advertisements: Draft copies of the package labeling and promotional material for the dietary supplement as well as a list of Scientific Publications are enclosed as Attachment 2.

We would appreciate your earliest attention to this submission. It is our understanding that upon the expiration of seventy six (76) days following your office's receipt of this notification and, absent any responsive commentary from your office, YAT CHAU will be able to market the dietary supplement in the United States.

Should you have any questions or comments regarding the enclosed information file, please do not hesitate to contact us.

Very truly yours,

Sherman Ye

Sherman Ye, Ph.D.

RECEIVED 7/10/02

一洲美國藥業集團有限公司
YAT CHAU (USA) INC.

131-37A, 41 AVE., 1FL.
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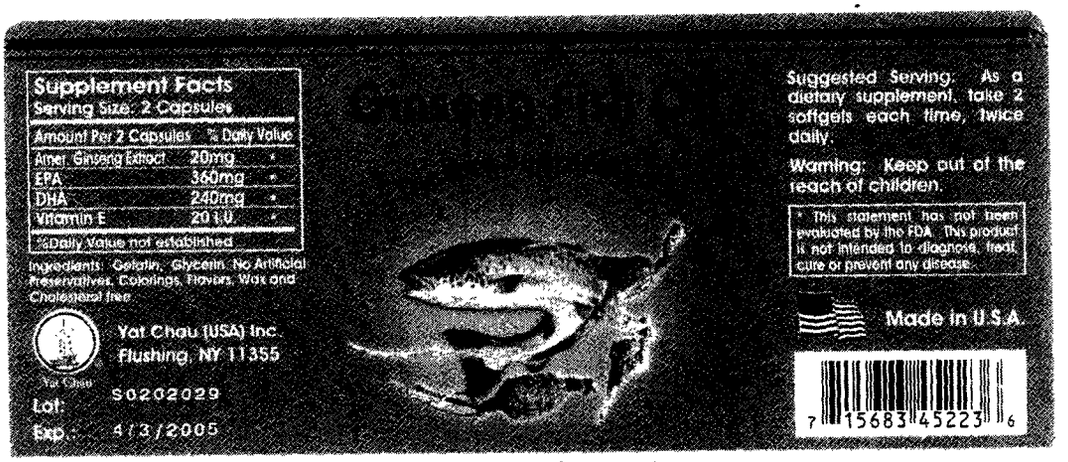

60 Softgels, 1000 mg each

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Immunomodulating activity of CVT-E002, a proprietary extract from North American ginseng (Panax quinquefolium).
J Pharm Pharmacol. 2001 Nov;53(11):1515-23.
PMID: 11732754 [PubMed - indexed for MEDLINE]

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Effects of ginseng supplementation on supramaximal exercise performance and short-term recovery.
J Strength Cond Res. 2001 Aug;15(3):290-5.
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Comp Biochem Physiol C Toxicol Pharmacol. 2001 Nov;130(3):369-77.
PMID: 11701393 [PubMed - indexed for MEDLINE]

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Phytomedicine. 2001 Sep;8(5):401-9. Review.
PMID: 11695885 [PubMed - indexed for MEDLINE]

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PMID: 11444574 [PubMed - indexed for MEDLINE]

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Biol Pharm Bull. 2001 Jun;24(6):638-42.
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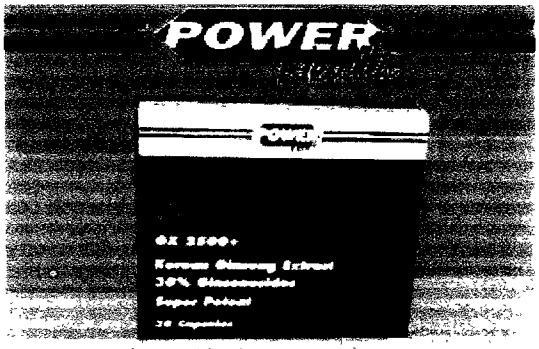

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