DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: JAN 23 2003

From: Consumer Safety Officer, 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: _Hi®DHA tuna oil_____

Firm: _Clover Corporation Limited
Represented by: Piper Marbury Rudnidk & Wolfe

Date Received by FDA: 4/08/02, amended 5/09/02_____

90-Day Date: 8/07/02_____

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.

V. Lutwak 1/15/03
CSO/Vickey Lutwak

R/D/HFS-821:CSO_VLutwak_____ Date 1/15/03 _____
DOC: found on "p" drive via pathway:

95S-0316

RPT 130

DSLRdata/DS Team/Confidential/HiDHA_____/Dockets Memo for Hi®DHA tuna oil

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

0412 '03 JAN 27 P2:03

July 23, 2002

Anthony L. Young
Piper Marbury Rudnick & Wolfe LLP
1200 19th Street, N.W.
Washington, DC 20036

Dear Mr. Young:

This is to inform you that the notification and amendment, dated April 5, 2002 and May 8, 2002 respectively, you submitted on behalf of your client Clover Corporation Limited pursuant to 21 U.S.C. 350b(a)(2) were received and filed by the Food and Drug Administration (FDA) on May 9, 2002. Your notification concerns the substance called "HiDHA® tuna oil" that you assert is a new dietary ingredient.

The notification explains that Clover Corporation Limited would serve as both the manufacturer and distributor of HiDHA® tuna oil as a bulk ingredient and source of omega-3 fatty acids for use by other companies in dietary supplements. The notification further states the intended daily intake of HiDHA® tuna oil in a dietary supplement should not exceed one gram per day. You informed us that one gram of HiDHA® tuna oil would deliver 250-280 mg of docosahexaenoic acid (DHA) and 50-80 mg of eicosapentaenoic acid (EPA) for a maximum combination of 360 mg DHA/EPA.

In accordance with 21 C.F.R 190.6(c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date (i.e., until after July 23, 2002), you must not introduce or deliver for introduction HiDHA® tuna oil into interstate commerce for use as a dietary ingredient in any dietary supplement.

Please note that acceptance of this notification for filing is a procedural matter and does not constitute a finding by the FDA that HiDHA® tuna oil or a dietary supplement containing it is safe or is not adulterated under 21 U.S.C. 342. Further, FDA is not precluded from taking action in the future against any dietary supplement containing HiDHA® tuna oil if it is found to be unsafe, adulterated or misbranded.

As another procedural matter, your notification will be kept confidential for 90 days after the filing date. Therefore, after August 7, 2002, the notification, its amendment 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.

Prior to August 7, 2002, you may wish to identify in writing specifically what information you believe is proprietary. Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notification should be redacted before it is posted at Dockets.

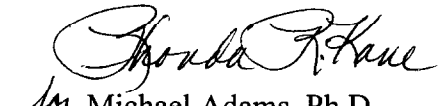
The FDA Internet site http://www.cfsan.fda.gov/~dms/ds-labl.html#structure provides details on the types of claims that are allowed for dietary supplements, including structure/function, health and nutrient content claims. Federal regulations at 21 CFR 101.36 address the general labeling requirements of all dietary supplements whether or not claims are made.

For claims that are allowed under 21 U.S.C. 343(r)(6) (e.g., those related to the structure or function of the human body or one's general well-being), a dietary supplement's labeling must include a specific disclaimer. In addition, no later than 30 days post marketing, the product's manufacturer or distributor must notify FDA in writing about a structure/function claim. Federal regulations at 21 CFR 101.93 specify the notification requirements for such claims. Label claim notification requirements are separate from those for the new dietary ingredient premarket notification program.

FTC Internet site http://www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm provides details on Federal requirements concerning the advertising of dietary supplements. All dietary supplement claims made in both product labeling and advertising must be substantiated with scientific evidence, be truthful, and not be misleading.

Please contact me at (301) 436-2371, if you have any questions concerning this matter.

Sincerely yours,



for Michael Adams, Ph.D.
Acting Team Leader
Dietary Supplements Team
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Strauss, Karen F

From: Strauss, Karen F
Sent: Monday, April 15, 2002 11:50 AM
To: 'hamishd@clovercorp.com.au'; 'anthony.young@piperrudnick.com'
Cc: Chang, Gloria; Kane, Rhonda R.; Satchell, Felicia B
Subject: New Dietary Ingredient Notification- HiDHA tuna oil

Importance: High
Sensitivity: Confidential

Mr. Hamish Drummond
Clover Corporation Limited
and
Mr. Anthony L. Young
Piper Marbury Rudnick & Wolfe

This is in response to your correspondence, dated April 5, 2002, to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 350b(a)(2). On April 8, 2002, FDA received and filed your notification that asserts that HiDHA tuna oil is a new dietary ingredient

Your notification submission is incomplete and does not meet the minimum requirements in 21 CFR § 190.6. Without the complete required information, we cannot assess the safety of your new dietary ingredient. For your convenience, we have attached a copy of the section of the CFR that addresses these requirements. There is also a website address http://www.cfsan.fda.gov/~dms/ds-ingrd.html that may further assist you in submitting the required information.

For example, the notification you sent us concerning HiDHA tuna oil does not comply with the requirements of 21 CFR § 190.6 because it fails to:

- specify the conditions of use, for example, you state that the "Dietary supplements containing HiDHA tuna oils will be labeled for daily intakes of up to 1.0 gram oil per day. The HiDHA 25S and 25F Softgel preparations contain 5 to 8% EPA and 25 to 28% DHA, or 30 to 35% EPA+DHA. At the higher levels, this would add 0.36 gram EPA+DHA to total exposure." What will be the label instructions for use, e.g., the amount of HiDHA per softgel, the number of softgels per serving or dose, and number of servings per day and the duration or limitation of use, if any, e.g., is the ingredient for intermittent use, e.g., one month at a time or for long-term or chronic use, etc. Please clarify. Are there special conditions of use for subpopulations, e.g., children, pregnant or lactating women; and
- provide photostatic copies or reprints of the published articles referenced in "Appendix 1: Expert Panel Report," pages 47-49 (e.g., citations to published articles must be accompanied by photostatic copies or reprints of the published articles in English) (See 21 CFR § 190.6). Three copies are required, but we would appreciate receiving a total of six copies.

The safety review will start only when all of the required technical information is submitted. If we receive the information before the 75 days, and we find it complete, the date we receive the new or amended notification will be the new filing date and the 75 days will begin from that date. Further, you may wish to identify what information in the NDI or amended notification you believe is proprietary. Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notification should be redacted before it is posted at Dockets.

Karen Strauss

Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition

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NDI notification.txt