DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: Oct. 27, 2003

From: Chemist, Division of Dietary Supplement Programs and Compliance, 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:	Conjugated Linoleic Acid (CLA) [Tonalin Brand]
Firm:	Chrsitopher & Weisberg, P.A. and Sidley Austin Brown & Wood, LLP for their client Natural ASA
Date Received by FDA:	June 17, 2002
90-Day Date:	September 15, 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 exceeds the 90-day date. Thank you for your assistance.

Kenneth M. P. Taylor, Ph.D.

Attachments

Victoria Witwack

95S-0316

RPT 162

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD

JUL 30 2002

Jason S. Crush
Christopher & Weisberg, P.A
Attorneys at Law
200 East Las Olas Boulevard
Suite 2040
Fort Lauderdale, Florida 33301

Dear Mr. Crush:

This is to inform you that the notification, dated June 10, 2002, which you submitted on behalf of your client, Natural ASA, pursuant to 21 U.S.C. 350b(a)(2) was received and filed by the Food and Drug Administration (FDA) on June 17, 2002. Your notification concerns the substance conjugated linoleic acid (CLA) that you assert is a new dietary ingredient.

Your notification further states that CLA is to be manufactured and/or distributed by Natural ASA under the trademark Tonalin in the form of 750 mg gelatin capsules. The expected daily intake of Tonalin is a maximum of 3.4 grams or 6 capsules, taken at intervals of two capsules three times per day. You identified a target population of adults as consumers of this product.

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., after August 31, 2002), your client must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains CLA.

Please note that acceptance of this notification for filing is a procedural matter and, thus, does not constitute a finding by FDA that the new dietary ingredient or supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. 342. FDA is not precluded from taking action in the future against any dietary supplement containing CLA (Tonalin) 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. After September 15, 2002, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information in the notification will not be disclosed to the public.

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.

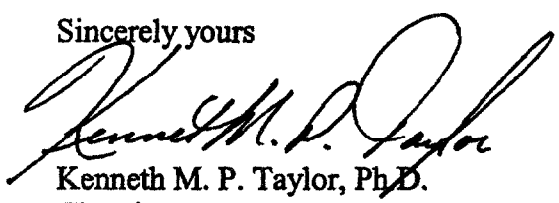
For claims that are allowed under 21 U.S.C. 343(r)(6) (e.g., those related to the structure or function of the human body or one's general well-being), a dietary supplement's labeling

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.

The 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



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