



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: OCT 19 2000
From: (Acting) Director, Division of Standards and Labeling Regulations, Office of
Nutritional Products, Labeling and Dietary Supplements, HFS-820
Subject: 75-Day Premarket Notification for New Dietary Ingredients
To: Dockets Management Branch, HFA-305

0793 '00 OCT 30 P1:48

New Dietary Ingredient: Zeaxanthin
Firm: Roche Vitamins, Inc.
Date Received by FDA: August 8, 2000
90-Day Date: November 6, 2000

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification for the aforementioned new dietary ingredient should be placed on public display in docket number 95S-0316 after November 6, 2000.

Felicia B. Satchell
Felicia B. Satchell

95S-0316

RPT81



OCT 19 2000

A. Davidovich, D.V.M., Ph.D., D.A.B.T.
Associate Director Regulatory Affairs
Roche Vitamins Inc.
45 Waterview Boulevard
Parsippany, New Jersey 07054-1298

Dear Dr. Davidovich:

This is in response to your letter to the Food and Drug Administration (FDA) dated August 3, 2000, making a submission for a new dietary ingredient pursuant to 21 U.S.C. 350b(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act). Your letter notified FDA of your intent to market a product containing a new dietary ingredient named zeaxanthin. FDA received your submission on August 8, 2000.

21 U.S.C. 350b(a)(2) requires that a manufacturer or distributor of a dietary supplement that contains a new dietary ingredient 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 21 U.S.C. 350b(a)(2), there must be a 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. 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.

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 the new dietary ingredient zeaxanthin will reasonably be expected to be safe. The information in your submission does not meet the requirements of 21 CFR §190.6(b)(3) because it does not contain a description of the dietary supplement that contains the new dietary ingredient including the level of the new dietary ingredient in the dietary supplement (see 21 CFR §190.6(b)(3)(i)), nor does it describe, in a quantitative manner, the amount to be consumed daily. The submission contains evidence of history of use and other information that you assert is an adequate basis to conclude that the dietary supplement containing the new dietary ingredients will reasonably be expected to be safe. However, the information in the submission is inadequate to make such a determination (see 21 CFR §190.6(b)(4)). The

submission provides insufficient information to enable a determination to be made that the levels and strength of zeaxanthin tested in the studies are relevant to determining whether your product, as formulated and at the expected exposure when used as suggested in labeling, would reasonably be expected to be safe. Furthermore, the submission fails to include the complete results of the unpublished toxicology studies that are needed to fully evaluate the safety of zeaxanthin. The submission fails to elucidate whether the recommended dietary supplement intakes are comparable to the amount of zeaxanthin consumed in a typical diet. This information is necessary to evaluate whether it is appropriate to extrapolate a safe level of supplementation from dietary exposure and whether additive exposure to zeaxanthin would be safe for adults or for children. In addition, the significance of some effects associated with zeaxanthin consumption whose adverse nature is unclear is not addressed.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that zeaxanthin, 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 ingredients do not present a significant or unreasonable risk of illness or injury. Introduction of such products into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Should you have any questions concerning this matter, please contact us at (202) 205-4168.

Sincerely yours,



Felicia B. Satchell
(Acting) Director
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements

cc:

HFA-305 (Docket No. 95S-0316 through HFS-22 (CCO)

HFS-605 (Field Programs)

HFS-800 (Lewis, Wilkening)

HFS-810 (Foret)

HRS-911 (Moore)

HFS-820 (Satchell)

HFS-821 (Carlson, Kane)

HFS-? (Bolger, Assinom)- toxicology

HFR

R/D:HFS-821:MCarlson:10/11/00

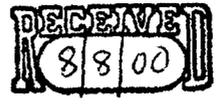


Vitamins

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VIA COURIER

August 3, 2000



Dr. Robert J. Moore
Office of Special Nutritionals (HFS-450)
Center for Food Science and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, DC 20204

Re: New Dietary Ingredient Notification: Zeaxanthin

Dear Dr. Moore,

Enclosed please find an original and three copies of the "Notification of the Marketing of a New Dietary Ingredient: Zeaxanthin", submitted pursuant to section 413 of the Federal Food, Drug and Cosmetic Act.

Please note that pursuant to 21 C.F.R. § 20.61, Roche Vitamins Inc. designates as confidential Section 1.3.3 "Manufacturing Principles" and Chapter 4 "Toxicology Summary".

Zeaxanthin is a carotenoid found in the retina (macula) of humans. Because humans cannot synthesize carotenoids, food is the only source, particularly from consumption of yellow/orange/ red fruits and dark green leafy vegetables.

The submission is divided in three volumes. Volume one contains the description, chemistry, nutritive effect and safety evaluation. We have included all the references cited; they are organized in alphabetical order and divided into two volumes: Volume two contains the references from A to K and volume three contains the references from L to Z.

Thank you for your attention to this matter. If you have any questions regarding to the notification, please do not hesitate to call me at the above number.

Sincerely,

A. Davidovich, DVM, PhD, DABT
Associate Director Regulatory Affairs

Enclosure