



Memorandum

*Rec'd 08-23-02
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Date: **AUG 16 2002**

From: Director, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-820

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

New Dietary Ingredient: Crossential SA14 (Echium oil)

Firm: Bioriginal Food & Science Corp.

Date Received by FDA: August 15, 2001

90-Day Date: November 13, 2001

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 as soon possible since it is past the 90-day date. Thank you for your assistance.

Felicia B. Satchell
Felicia B. Satchell

95S-0316

RPT/100



AUG 23 2001

Rakesh Kapoor, Ph.D.
Product Development Manager
Bioriginal Food & Science Corp.
102 Melville Street, Saskatoon
Saskatchewan, Canada S7J 0R1

This is to inform you that the notification, dated August 13, 2001, you submitted pursuant to 21 U.S.C. 350b(a)(2) was received and filed by the Food and Drug Administration (FDA) on August 15, 2001. Your notification concerns the substance Crossential SA14 that you describe as a pure triglyceride extracted from the seeds of the *Echium plantagineum* plant and that you assert is a new dietary ingredient.

21 U.S.C. 350b(a)(2) requires that a manufacturer or distributor of a dietary supplement that contains a new dietary ingredient submit certain information to FDA at least 75 days before the dietary ingredient is introduced or delivered for introduction into commerce. This information must include 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 section 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 new dietary ingredient 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 and injury.

21 CFR § 190.6 specifies the requirements for a premarket notification on a new dietary ingredient. These Federal regulations state that any reference to published information offered in support of the notification must be accompanied by reprints or photostatic copies of such references. If any part of the materials submitted is in a foreign language, it also must be accompanied by an accurate and complete English translation. In addition, an original and two copies of all documentation pertaining to a notification must be submitted to FDA.

We conducted an initial screening of the packet of information you sent us and determined that it does not comply with 21 CFR § 190.6. We identified several references cited on pages 20-23 of your notification that are absent or have missing pages. Please see the list below for details:

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- Missing copies of reference numbers 11, 17, 18, 45, 60 and 75.
- Missing page 1 of reference number 72 found after the cover sheet identifying it as a European Patent Application. We believe that page 1 would begin with a narrative preceding the flow diagram.
- Missing pages 1 and 4 of reference number 74 of a European Patent Specification. Again we believe that page 1 would begin with a narrative. The copies you sent to us contained duplicates of page 5 instead.

In addition, reference numbers 40 and 66 and pages 37 and 38 of your notification were written in a foreign language and are not accompanied by accurate and complete English translations. Please also note that the type size of some of the printed information on page 37 of your notification is too small to read.

Because your current notification does not meet the minimum requirements of 21 CFR § 190.6, FDA did not review the evidence of safety information you submitted on Crosssential SA14. You are welcome to send us the missing information to correct the deficiencies in your current notification. If you prefer, you can elect instead to send us a new notification that is complete and fully complies with 21 CFR § 190.6. We will review the safety information for Crosssential SA14 upon receipt of the missing information or a new complete notification. If you opt to amend your current notification by providing us with the missing documents in triplicate, we will revise the notification's filing date, which will be the date FDA receives this information.

For the reasons discussed above, the information in your notification does not provide an adequate basis to conclude that Crosssential SA14, 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 the Crosssential SA14 for which there is inadequate information to provide reasonable assurance that it does 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).

Your notification will be kept confidential for 90 days from the date of its receipt. After November 13, 2001, your notification 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 in the notification will not be disclosed to the public. For FDA's consideration, you may wish to identify in writing specifically what information you believe is proprietary in your current notification or in any amended or new notification

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you may send us. 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.

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

Sincerely yours,


For 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