



DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Public Health Service

Memorandum

MAR - 3 2000

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Date .
From Senior Regulatory Scientist, Regulatory Branch, Division of Programs & Enforcement Policy (DPEP), Office of Special Nutritionals, HFS-456
Subject 75-day Premarket Notification for New Dietary Ingredient
To Dockets Management Branch, HFA-305

New Dietary Ingredient: *Haematococcus pluvialis* algae
Firm: Aquasearch, Inc.
Date Received by FDA: December 16, 1999
Amendment 1 Received: February 11, 2000
Amendment 2 Received: February 22, 2000
90-day Date: May 21, 2000

In accordance with the requirements of section 413(a)(2) 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 May 21, 2000.


Robert J. Moore, Ph.D.

95S-0316

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAR - 3 2000 3 19 6 '00 MAR -7 P2:37

Mr. Martin Guerin
V.P. Marketing & Sales
Aquasearch, Inc.
73-4460 Queen Kaahumanu Highway
Suite 110
Kailua-Kona, Hawaii 96740

Dear Mr. Guerin:

This is to notify you that your submission pursuant to section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) dated December 6, 1999, concerning the marketing of a substance that you assert is a new dietary ingredient (i.e., *Haematococcus pluvialis* algal meal containing astaxanthin), was received by the Food and Drug Administration (FDA) on December 16, 1999. FDA received amendments to your submission on February 11 and February 22, 2000. On February 23, 2000, we notified you that your February 22, 2000 amendment was substantive and that its date of receipt would constitute the filing date for your submission.

Your submissions will be kept confidential for 90 days from the date of receipt, and after May 21, 2000, your submission will be placed on public display at Dockets Management Branch (Docket No. 95S-0316). Commercial and confidential information in the notification will not be made available to the public.

Please contact us if you have questions concerning this matter.

Sincerely,

Robert J. Moore, Ph.D.
Acting Chief, Dietary Supplements Branch
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements



FEB 23 2000 3 19 7 '00 MAR -7 P2:37

Mr. Martin Guerin
V.P. Marketing & Sales
Aquasearch, Inc.
73-4460 Queen Kaahumanu Highway
Suite 110
Kailua-Kona, Hawaii 96740

Dear Mr. Guerin:

This is to notify you that the amendment, dated February 16, 2000, to your submission pursuant to section 413(a)(2) (21 U.S.C. 350b(a)(2)) of the Federal Food, Drug, and Cosmetic Act (the Act) concerning the marketing of a substance that you assert is a new dietary ingredient (i.e., *Haematococcus algae*) was received by the Food and Drug Administration (FDA) on February 22, 2000.

In accordance with 21 CFR 190.6(d), this letter is to notify you that FDA has determined that the new submission is a substantive amendment and, accordingly, the new filing date for your submission is February 22, 2000.

Under 21 U.S.C. 350b(a), 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 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. A dietary supplement that contains a new dietary ingredient is considered adulterated under 21 U.S.C. 342(f)(1)(B) if it is introduced into interstate commerce less than 75 days after submitting such a notification. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v). Therefore, you should not introduce a dietary supplement containing the new dietary ingredient that is the subject of your submission before 75 days after the new filing date for your submission.

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Please contact us if you have questions concerning this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert J. Moore". The signature is written in a cursive style with a large, prominent initial "R".

Robert J. Moore, Ph.D.

Acting Chief

Dietary Supplements Branch

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling,

and Dietary Supplements

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington DC 20205



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73-4460 Queen Kaahumanu Highway
Suite 110, Kailua-Kona, HI 96740 USA
Tel: (808)326-9301 Fax: (808)326-9401
WebSite: <http://www.aquasearch.com/>
E-mail: aqse@aquasearch.com

December 6, 1999

Re: New Dietary Ingredient Notification for *Haematococcus* algae.

Dear Administrator,

According to rule 21 CFP Subpart B 190.6, we are sending you two notifications in the attached documents. The first is for a New Dietary Ingredient Notification for *Haematococcus pluvialis* algal meal (Section 1 and 2), and the second is a New Dietary Supplement Notification for The AstaFactor™ - Softgels – 5mg (Section 3 and 4). Throughout these two applications, terms such as *Haematococcus pluvialis*, *H. pluvialis*, *Haematococcus*, are to be considered equivalent and interchangeable. Although these are two separate applications, since they share a large part of the supporting documentation (Sections 5 to 9), they have been regrouped in the same folder.

We plan to market both products 75 days after the acknowledgement of receipt of this notice, unless otherwise instructed by your agency.

Please find enclosed one original and two copies of these two notifications.

Thank you very much in advance for the attention that you will give to our notification. If you have any question, do not hesitate contacting us at 808-326 9301.

Sincerely yours,


Martin Guérin
V.P. Marketing & Sales
Aquasearch Inc.

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1. 75-day notification letter to FDA for a new ingredient for dietary supplement:
Aquasearch's *Haematococcus pluvialis* algal meal.
2. Aquasearch's *Haematococcus pluvialis* algal meal specifications, label, and description of manufacturing process.
3. 75-day notification letter to FDA for new dietary supplement:
AstaFactor™ softgels –5mg
4. AstaFactor™ softgels specifications, label and description of manufacturing process.
5. Safety data
 - 5.1. Review: TR.3005.001
 - 5.2. Human safety study: RD.0100.001
 - 5.3. Rat toxicity study: report by MBR Laboratories
 - 5.4. Analyses results: algal meal, test materials.
6. Astaxanthin technical reports
7. Stability studies
8. Analytical methods
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