



**Memorandum**

*Rec'd 8/20/02  
jib*

Date: **AUG 23 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: phytic hexacitrate

Firm: Scientific Medical Devices, Inc.

Date Received by FDA: November 1, 2001

90-Day Date: January 30, 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 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

Attachments

*95S-0316*

*RPT104*



NOV 15 2001

Mr. Kent H. Kohnken  
President & CEO  
Scientific Medical Devices, Inc.  
6160 Wellington Court  
Cumming, Georgia 30040-7029

Dear Mr. Kohnken:

This is to inform you that the notification, dated September 14, 2001, you submitted pursuant to 21 U.S.C. 350b(a)(2) was received and filed by this office of the Food and Drug Administration (FDA) on November 1, 2001. The notification concerns the substance "phytic hexacitrate" that you describe as a complex of phytic acid and citric acid 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.

Federal regulations found at 21 CFR § 190.6 specify the requirements for a premarket notification on a new dietary ingredient. A copy of this section is enclosed for your reference. The notification you sent us concerning phytic hexacitrate does not comply with the requirements of 21 CFR § 190.6 because it fails to:

- sufficiently describe phytic hexacitrate (e.g., identify if it is a compound and its chemical structure, formula, and properties),
- specify the level of phytic hexacitrate that would be contained in a dietary supplement,

- specify the conditions of use recommended or suggested in the labeling of a dietary supplement containing phytic hexacitrate or the ordinary conditions of use of such a dietary supplement,
- provide a history of use or other evidence of safety establishing that phytic hexacitrate when used as indicated in the labeling or under ordinary conditions of use is reasonably expected to be safe,
- provide citations to published articles, copies of references, or any other information that you used as a basis for the above stated safety determination, and
- provide the notification in triple (i.e., one original and two copies).

You are welcome to send us the required information to correct the deficiencies in your current notification. If you prefer, you instead can elect to send us a new notification that is complete and fully complies with 21 CFR § 190.6. Upon receipt of this information, we will revise the notification's filing date, which will be the date this office of FDA receives the additional information. Please see the enclosed reference for our mailing address.

For the reasons discussed above, the information in your notification does not provide an adequate basis to conclude that the use of phytic hexacitrate in a dietary supplement is 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 phytic hexacitrate 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, January 30, 2002, 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.

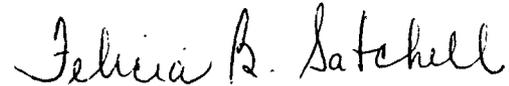
If you do send FDA a new or amended notification, you may wish to identify in writing specifically what information you believe is proprietary. Nevertheless, our Center's Freedom

Page 3 – Mr. Kent H. Kohnken

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,

A handwritten signature in cursive script that reads "Felicia B. Satchell".

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

Enclosure



# Code of Federal Regulations

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## 21

Part 170 to 199

Revised as of April 1, 2001

### Food and Drugs

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Containing a codification of documents  
of general applicability and future effect

As of April 1, 2001

*With Ancillaries*

Published by  
Office of the Federal Register  
National Archives and Records  
Administration

A Special Edition of the Federal Register



accompanied by reprints or photostatic copies of such references. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation; and

(5) The signature of the person designated by the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient.

(c) FDA will acknowledge its receipt of a notification made under section 413 of the Federal Food, Drug, and Cosmetic Act (the act) and will notify the submitter of the date of receipt of such a notification. The date that the agency receives the notification submitted under paragraph (a) of this section is the filing date for the notification. For 75 days after the filing date, the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient shall not introduce, or deliver for introduction, into interstate commerce the dietary supplement that contains the new dietary ingredient.

(d) If the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient, or of the new dietary ingredient, provides additional information in support of the new dietary ingredient notification, the agency will review all submissions pertaining to that notification, including responses made to inquiries from the

agency, to determine whether they are substantive and whether they require that the 75-day period be reset. If the agency determines that the new submission is a substantive amendment, FDA will assign a new filing date. FDA will acknowledge receipt of the additional information and, when applicable, notify the manufacturer of the new filing date, which is the date of receipt by FDA of the information that constitutes the substantive amendment.

(e) FDA will not disclose the existence of, or the information contained in, the new dietary ingredient notification for 90 days after the filing date of the notification. After the 90th day, all information in the notification will be placed on public display, except for any information that is trade secret or otherwise confidential commercial information.

(f) Failure of the agency to respond to a notification does not constitute a finding by the agency that the new dietary ingredient or the dietary supplement that contains the new dietary ingredient is safe or is not adulterated under section 402 of the act.

[62 FR 49891, Sept. 23, 1997, as amended at 66 FR 17359, Mar. 30, 2001]

**PARTS 191-199 [RESERVED]**

A list of CFR titles  
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 Table of CFR Title  
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC

October 31, 2001

Kent H. Kohnken  
Scientific Medical Devices, Inc.  
6160 Wellington, Court  
Cumming, GA 30040-7029

Thank You for your interest in the Food and Drug Administration (FDA). The Center for Food Safety and Applied Nutrition, known as CFSAN, is one of six product-oriented centers, in addition to a nationwide field force, that carry out the mission of the Food and Drug Administration (FDA). CFSAN is a regulatory agency responsible for the safety of the nation's domestically produced and imported foods and cosmetics sold and purchased through interstate commerce. It is one of the oldest federal agencies whose primary function is consumer protection. I have forwarded your notification to the Office of Nutritional Products, Labeling, and Dietary Supplements. You may reach that office at (202) 205-4168. For additional information, you may visit our website at [www.FDA.gov](http://www.FDA.gov).

Thank you,

A handwritten signature in black ink that reads "Regina M. Curry". The signature is written in a cursive style with a large initial "R" and "C".

Regina Curry  
Public Affairs Specialist  
1-888-SAFEFOOD

**SCIENTIFIC MEDICAL DEVICES, INC.**

**6160 Wellington Court  
Cumming, GA 30040-7029**

**Phone: (770) 889-6240**

**Fax: (770) 889-3335**

**Email: kkohnken@bellsouth.net**

From CES 10-31-01  
Forwarded TO  
ONPLDS  
205-4168

**September 14, 2001**

**Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857-0001**

HFS-820

**Re: New Dietary Ingredients**

**Dear Sir:**

**Pursuant to the rules contained in the "Dietary Supplement Health and Education Act of 1994", we are notifying you of our attention to offer for sale 75 days from your receipt of this communication, Phytic hexacitrate.**

**Phytic hexacitrate is a complex of two ingredients that are each well known to be safe:**

**Phytic Acid  
Citric Acid**

**Best regards,**



**Kent H. Kohnken  
President & CEO**