DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

APR -2 2003 712 '03 APR -4 P4:27

Ms. Beth Thompson
Global Regulatory Affairs Manager
Kemin Consumer Care, L.C.
600 East Court Avenue
Suite A
Des Moines, Iowa 50309-2021

Dear Ms. Thompson:

This is in response to your letter of March 20, 2003 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter notified FDA of claims you intend to make in the labeling of the product Satise™. The product contains a dietary ingredient you identify as potato protein extract.

This letter is to inform you that FDA believes that you are required to submit a notification pursuant to 21 U.S.C. 350b and 21 CFR 190.6 for a product containing potato protein extract before marketing a dietary supplement containing this dietary ingredient. Based on the limited information in your submission, it appears that the potato protein extract dietary ingredient in your product is a new dietary ingredient within the meaning of 21 U.S.C. 350b(c) in that it is not a dietary ingredient that was marketed in the United States prior to October 15, 1994. Moreover, it appears that your potato protein extract dietary ingredient 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," within the meaning of 21 U.S.C. 350b(a)(1).

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. 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 new 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. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

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The mere incidental presence of components of your product in food marketed in the United States before October 15, 1994 does not mean that the dietary ingredient is not a new dietary ingredient defined in 21 U.S.C. 350b(c) nor that it is a dietary ingredient that has been present in the food supply as an article used for food in a form in which the food has not been chemically altered, a fact that would preclude the necessity of a notification (see 21 U.S.C. 350b(a)(1)). In order to establish that potato protein extract dietary ingredient qualifies as an "article used for food in a form in which the food has not been chemically altered" within the meaning of 21 U.S.C. 350b(a)(1), you would have to show that the dietary ingredient itself has been used as a food or as an ingredient in a food, without chemical alteration. The mere incidental presence of components of potato protein extract or potato protein extract itself as inherent components of articles used for food does not establish that section 350b(a)(1) applies. Therefore, your product is dietary supplement that contains a new dietary ingredient for which a notification is required under 21 U.S.C. 350b(a)(2) and 21 CFR 190.6.

Please contact us if you have any questions regarding this matter.

Sincerely yours,

for Susan J. Walker, M.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Office of Compliance, Center for Drug Evaluation and Research, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Kansas City District Office, Office of Compliance, HFR-SW340

Kemin Consumer Care, L.C.
600 E. Court Ave., Suite A
Des Moines, Iowa 50309-2021 USA
tel: 515.248.4000 fax: 515.248.4050
toll free: **877.472.8473**
www.satise.com

March 20, 2003

Office of Nutrition Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
Harvey W. Wiley Building
HFS-810
College Park, MD 20704

Re: Section 403(r)(6) Dietary Supplement Notification

To Whom It May Concern:

Pursuant to Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) we are notifying the Food and Drug Administration (FDA) that we have introduced into interstate commerce a dietary supplement that contains a structure/function claim. We are providing the following information as required by 21 CFR 101.93(a)(2):

1. **Name and Address of the Manufacturer:**

   Kemin Consumer Care, L.C.
   600 East Court Avenue, Suite A
   Des Moines, Iowa 50309-2021
   United States
   515.248.4000 Phone
   515.248.4050 Fax

2. **Text of the Statement:**

   The following statement appears on the label of Satise™:

   "Helps produce feeling of fullness to manage hunger naturally!"

83848

3. **Name of the Dietary Ingredient**

   Each 30-count package of Satise™ contains 30 capsules that are to be taken twice per day. Each capsule contains 15 mg of the potato proteinase inhibitor PI2.

   Each 60-count package of Satise™ contains 60 capsules that are to be taken twice per day. Each capsule contains 15mg of the potato proteinase inhibitor PI2.

4. **Name of Dietary Supplement:**

   Satise™

I certify that the information contained in the notice is complete and accurate, and that Kemin Consumer Care, L.C. has substantiation that the statements are truthful and not misleading.

If you have any questions on this or other matters, please contact us.

Sincerely,

Beth Thompson
Global Regulatory Affairs Manager

Satise™ Satiety Aid: Helps produce feelings of fullness to manage hunger naturally†.

Supplement Facts

Serving size:	1 capsule
Servings per package:	30 capsules
Amount Per Capsule	
Potato Protein Extract	15 mg*

*Daily value not established

Other Ingredients: Microcrystalline cellulose, Silicon dioxide, and Magnesium stearate

Daily Directions: Take one capsule approximately 30 minutes before the two largest meals.

Manufactured for Kevin Consumer Care, L.C., Des Moines, Iowa 50309

50100 01/22/99

Satise™

As with any weight management or exercise program, consult your physician. Pregnant or lactating women should consult their physician before using this or any product. May cause headaches or gastrointestinal symptoms. Results may vary.

Keep this product out of reach of children. Store in a cool dry place. Do not use if blister pack seal is broken.

Satise™

Satise™

SATÍSE™ SATIETY AID IS:
Clinically tested • Natural • Convenient

Helps produce feelings of fullness to manage hunger naturally†.

Satise™

FOR WEIG
MANAGEM

SATIETY AID • DIETARY SUPPLEMENT

Helps produce feelings of fullness
to manage hunger naturally†.

Satise™

SATIETY AID · DIETARY SUPPLEMENT

FOR W
MANAG

60 capsules

Satise™

As with any weight management or exercise program, consult your physician. Pregnant or lactating women should consult their physician before using this or any product.

May cause headaches or gastrointestinal symptoms. Results may vary.

Keep this product out of reach of children. Store in a cool dry place. Do not use if blister pack seal is broken.

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Satise™ Satiety Aid: Helps produce feelings of fullness to manage hunger naturally†.

Supplement Facts

Serving size:	1 capsule
Servings per package:	60 capsules
Amount Per Capsule	
Potato Protein Extract	15 mg*
*Daily value not established	

Other Ingredients: Microcrystalline cellulose, Silicon dioxide, and Magnesium stearate

Daily Directions: Take one capsule approximately 30 minutes before the two largest meals.

Satise™

SATIETY AID IS:

www.satise.com

Satise™ Satiety Aid is:

Satiety Aid

SATISE™ SATIETY AID IS: