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OCT 11 2006

Susan B. Hardwicke, Ph.D.
President and CEO
KSERO Corporation, Inc.
4200 Innslake Drive
Suite 101
Glen Allen, Virginia 23060

Dear Dr. Hardwicke:

This is in response to your letter of September 19, 2006 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 submission states that KSERO Corporation, Inc. is marketing the product Smart Cookie™ as a dietary supplement.

21 U.S.C. 321(ff) defines the term "dietary supplement." As defined by the Act, a dietary supplement does not include a product represented for use as a conventional food or as a sole item of a meal or the diet. 21 U.S.C. 321(ff)(2)(B). The product identified above is represented for use as a conventional food (i.e., as a cookie) (i.e., it is identity labeled as a cookie and it is described as a "gourmet cookie" in claims made for the product). Therefore, in that it is represented for use as a conventional food, it is not a dietary supplement within the meaning of 21 U.S.C. 321(ff) and claims made for it are not subject to 21 U.S.C. 343(r)(6).

Instead, this product appears to be a conventional food that must meet the regulatory requirements that apply to conventional foods rather than those requirements that apply to dietary supplements. Briefly, it must bear nutrition labeling in accordance with 21 CFR 101.9 and claims may be made for the product in its labeling if they are claims defined by 21 U.S.C. 343(r)(1) or 21 U.S.C. 321(g)(1)(C) that may be made for conventional foods. Additionally, under the Act, any ingredient intentionally added to a conventional food must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or an approved food additive causes a food to be adulterated under 21 U.S.C. 342(a)(2)(C) and cannot be legally marketed in the U.S. If you intend to market this product as a conventional food and you have any questions about the status of any of its ingredients, you should direct them to FDA's Office of Food Additive Safety (HFS-200), 5100 Paint Branch Parkway, College Park, MD 20740.

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Please contact us if we may be of further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

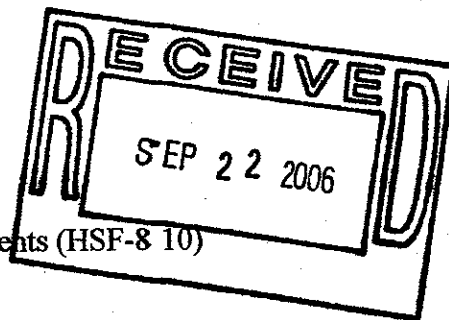
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Baltimore District Office, Office of Compliance, HFR-CE240



kSero

CENTERS FOR THE MIND

September 19, 2006



Office of Nutritional Products, Labeling and Dietary Supplements (HSF-8 10)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: KSERO CORPORATION ("KSERO")
30 Day Notice Letter under 403(r)(6) of DSHEA

Gentlemen:

This letter is being submitted pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 ("DSHEA") codified at 21 U.S.C. 343 (r)(6):

As required by 21 CFR 101.93(a)(2), KSERO submits the following information:

1. The name and address of the manufacturer of the dietary supplement that bears the statements is:

	<u>Manufacturer</u>
Name:	DeFazio's Catering
Address:	2601 Tuckernuck Dr.
City, State, Zip:	Richmond, VA 23294

2. The text of the statements that are being made are as follows:
 - a. "The gourmet cookie that gives you energy and focus"
 - b. "Improves focus and energy without a sudden drop in concentration."
3. Dietary ingredients that are the subject of the statements are:
 - Royal Jelly
 - Lecithin
 - Honey
 - Ribonucleic Acid
 - Cocoa
4. The statements appear on the labeling on the dietary supplement marketed under the brand name "SMART COOKIE™".

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2006-7479

I hereby certify that the information contained in this notice is complete and accurate and that KSERO has substantiation that the statements in this notice are truthful and not misleading.

Should you have any questions about this notice, please contact the undersigned at 804-747-9505.

Sincerely,

KSERO CORPORATION, INC



Susan B. Hardwicke, PhD
President and CEO