



4351 '01 MAY 15 P 2 :30

MAY - 1 2001

Karen A. Weaver, Esq.  
Weaver & Amin  
150 North Wacker Drive  
Suite 2020  
Chicago, Illinois 60606

Dear Ms. Weaver:

This is in response to your letter of March 29, 2001 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)) on behalf of Pure Life Sciences, Inc., of Chatsworth, California. Your submission states that Pure Life Sciences, Inc. is making the following claim for the product **Daily ProBalance**:

“Helps maintain blood sugar levels.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, cure or mitigate diseases, namely disorders related to blood glucose levels. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA’s Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

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Please contact us if we may be of further assistance.

Sincerely,



John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

copy:

Ms. Cheryl Richitt  
President  
Pure Life Sciences, Inc.  
9540 Cozycroft Avenue  
Chatsworth, California 913 11

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, San Francisco District Office, Office of Compliance, HFR-PA140

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-8 10 (Foret)

HFS-8 11 (r/f, file)

HFD-40 (Behrman)

HFD-3 10

HFD-3 14 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF- 1 (Nickerson)

f/t:HFS-811:rjm:4/20/01:docname:75432.adv:disc57

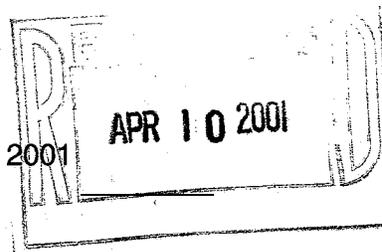
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Karen A. Weaver, J.D., R.Ph.  
Rakesh M. Amin, LL.M., R.Ph.

March 29, 2001



Charles A. Rego, J.D.  
Peter Malo, J.D., Ph.D.\*  
Gokul Kishan, LL.M.\*

*Of Counsel*

Michael L. Clerkin, LL.M.  
Radha Kurra, LL.M.\*

\*Not yet admitted to the Bar

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW  
Washington, D.C. 20204

Re: **Notification of Statements of Nutritional Support**

Dear Sir:

Enclosed is the original and two copies of an executed notification of Statements of Nutritional Support as required under section 101.93 of 21 Code of Federal Regulations and section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, as Amended.

If necessary, please address future correspondence to our firm.

Very truly yours,

Karen A. Weaver

KAW:Imr

Enclosures

Office of Special Nutritionals (HFS-450)  
Center for Food and Safety and  
Applied Nutrition  
Food and Drug Administration  
200 C Street, SW  
Washington, DC 20204



**Re: Statements of Nutritional Support**

Dear Sir:

Consider the following as notification of Statements of Nutritional Support as required under Section 403(r)(6) (21 U.S.C. 343(r)(6) of the Federal Food, Drug and Cosmetic Act and in accordance with Section 101.93 of 21 Code of Federal Regulations.

Distributor Name & Address: Pure Life Sciences  
9540 Cozycroft Ave.  
Chatsworth, CA 91311

<u>Statement Text</u>	<u>Name of Subject Dietary Ingredient(s)</u>	<u>Brand Name</u>
"Helps Maintain Blood Sugar Levels"	Chromium, Gymnema Sylvestre Extract, Alpha Lipoic Acid, Corosolic Acid	Daily ProBalance

The information contained in this notice is complete and accurate. The above distributor has substantiation that the statements are truthful and not misleading.

A handwritten signature in cursive script, appearing to read "Cheryl Richitt". The signature is written in black ink and is positioned above a horizontal line.

Ms. Cheryl Richitt  
President  
Pure Life Sciences, Inc.