

MAY 31 2001

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

Dear Ms. Weaver:

This is in response to your letter dated May 17, 2001 to the Food and Drug Administration (FDA) on behalf of Pure Life Sciences, Inc. of Chatsworth, California. In your letter, which responded to a letter from FDA dated May 1, 2001, you stated that you disagreed with the determination by FDA that the claim "helps maintain blood sugar levels" is a disease claim and not a claim that may be made for a dietary supplement pursuant to 21 U.S.C. 343(r)(6).

In our May 1, 2001 letter, we stated that the claim "helps maintain blood sugar levels" would not be an appropriate structure/function claim under 21 U.S.C. 343(r)(6). In the preamble to the January 6, 2000 final rule (see 65 FR 1000), FDA stated that general health maintenance claims that do not imply disease treatment or prevention would be acceptable structure function claims. We stated that if the health maintenance claim did not use terms that are so closely identified with a specific disease or that so clearly referred to a particular at-risk population, we believed that such a claim could be a structure/function claim under 21 U.S.C. 343(r)(6) (see discussion at 65 FR 1018).

You stated in your letter that your client's claim "helps maintain blood sugar levels" is an appropriate structure/function claim that does not imply disease treatment, prevention, or mitigation. We disagree that this claim is an appropriate structure or function claim because the context of the claim does not establish that the product is not intended to treat, prevent, or mitigate blood glucose levels that are abnormal. However, analogous to the situation for claims about blood cholesterol levels, a claim that a product is important or plays a role in the maintenance or regulation of blood glucose that is already normal or within normal limits could be an appropriate structure/function claim, depending on the context. As we discussed in the preamble to the final rule, the context in which a particular claim is made is important in determining whether a claim may be a disease claim or a structure/function claim. Consequently, if the context of a claim about a product intended to affect blood glucose clearly and unambiguously makes clear that the product is not intended to have an affect on abnormal blood glucose, such a claim may be an acceptable structure/function claims under

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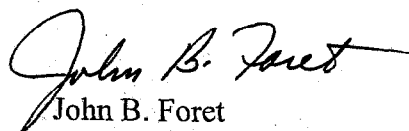
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21 U.S.C. 343(r)(6). But, the claim that your client proposed making for its product contained no such context and, consequently, is not an acceptable structure/function claim under 21 U.S.C. 343(r)(6). Moreover, the mere inclusion of the term "healthy" in the claim would not remedy the effect on disease by the product that is implied by the subject claim.

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

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, Los Angeles District Office, Compliance Branch, HFR-PA240

Copy:

Ms. Cheryl Richitt

President

Pure Life Sciences, Inc.

9540 Cozycroft Avenue

Chatsworth, California 9311

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cc:

HFA-224

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-810 (Foret)

HFS-811 (Moore, w/original incoming)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF-1 (Nickerson)

r/d:HFS-811:RMoore:5/22/01

Init:HFS-810:Foret:5/25/01

Init:HFS-800:CLewis:5/25/01

f/t:5/30/01:purelife.adv.adv:disc57

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May 17, 2001

Mr. John B. Foret
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C Street, SW
Washington, D.C. 20204

Via Regular Mail

Re: Notification of Statements of Nutritional Support

Dear Mr. Foret:

This communication responds to your May 1, 2001 correspondence advising my client, Pure Life Sciences, that its structure / function claim may be in violation of 21 U.S.C. 343 (r)(6).

The claim was submitted to FDA as "Helps maintain blood sugar levels". In actuality, the labeled claim is "Helps maintain healthy blood sugar levels". This is an acceptable claim as stated by the FDA in the docketed version of its final rule, Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body.

We apologize for this oversight and assume that this matter is closed.

Sincerely,

Karen A. Weaver

Cc: Ms. Cheryl Richitt
Pure Life Sciences