



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

1032 '01 APR 13 P3:21

MAR 21 2001

Ms. Katie Ferren
Marketing Director
Soft Gel Technologies, Inc.
6982 Bandini Boulevard
Los Angeles, California 90040-3326

Dear Ms. Ferren:

This is in response to your letter to the Food and Drug Administration (FDA) dated March 6, 2001. In your letter, which responded to a letter from FDA dated February 22, 2001, you stated that you had changed a claim that the product Glucosol "...helps balance blood glucose [sugar] levels..." to "...maintains healthy blood glucose levels." This letter is to advise you that we believe that the revised claim is not a claim that may be made for dietary supplements pursuant to 21 U.S.C. 343(r)(6).

In our February 22, 2000 letter, we stated that the claim "...helps balance blood glucose [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 revised your original claim to read, in part, "maintains healthy blood glucose levels," presumably on the basis that you believe that it is an appropriate structure/function claim that does not imply disease treatment, prevention, or mitigation. We disagree that the revised 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 (for example, then such a claim may be an acceptable structure/function claims under 21 U.S.C. 343(r)(6). But, the claim you are making for your product contains no such context and, consequently, is not an acceptable structure/function claim under 21 U.S.C. 343(r)(6).

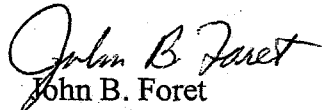
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example, then such a claim may be an acceptable structure/function claims under 21 U.S.C. 343(r)(6). But, the claim you are making for your product contains no such context and, consequently, is not an acceptable structure/function claim under 21 U.S.C. 343(r)(6).

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

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cc:

Federal Trade Commission

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:3/14/01

f/t: __/__/01:74881.adv:disc55

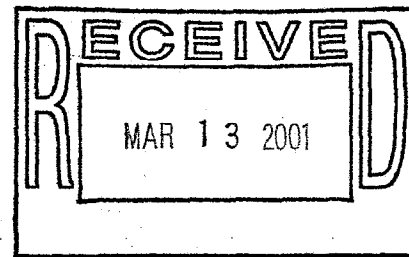
SOFT GEL

TECHNOLOGIES, INC.™

March 6, 2001

John Foret
Director, Office of Special Nutritionals
200 C, Street SW
Washington DC, 20204

74881



Dear Mr. Foret,

Thank you for your letter advising us against using the phrase "helps balance blood glucose [sugar] levels" with our Glucosol nutritional supplement (letter enclosed) in the side panel copy. We would like to re-submit the product with the following changes:

We are offering for sale the following product Pure Gel Glucosol™, with the following Structure Function claims: Maintains Healthy Blood Glucose Levels and Assists in Weight Management. The supporting side panel story is: Glucosol™ is a unique soft gel formulation containing the herb Lagerstroemia Speciosa L. Clinical data shows Glucosol™ maintains healthy blood glucose levels and assists in weight management.

We have deleted the reference to "balancing" blood sugar levels.

The FDA disclaimer will also appear on the label.

Sincerely,

A handwritten signature in cursive script, appearing to read "Katie Ferren".

Katie Ferren
Marketing Director
SGTI



FEB 22 2001

Ms. Katie Ferren
Marketing Director
Soft Gel Technologies, Inc.
6982 Bandini Boulevard
Los Angeles, California 90040-3326

Dear Ms. Ferren:

This is in response to your letter of January 19, 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)). Your submission states that Soft Gel Technologies, Inc. is making the following claim, among others, for the product **Glucosol™**:

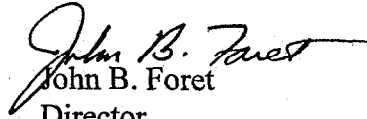
“...helps balance blood glucose [sugar] levels...”

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 disease, namely disorders of 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
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