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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.

975 0163 LET 451

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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

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, Office of Compliance, HFR-PA240

cc:

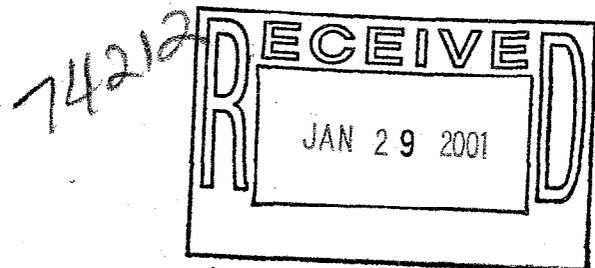
HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-800 (r/f, file)  
HFS-810  
HFS-811 (file)  
HFD-310  
HFD-314 (Aronson)  
HFS-605  
HFV-228 (Benz)  
GCF-1 (Nickerson)  
f/t:HFS-811:rjm:2/16/01:docname:74212.adv:disc54

# SOFT GEL

TECHNOLOGIES, INC.™

January 19, 2001

Dr. Elizabeth Yetley  
Director, Office of Special Nutritionals  
200 C, Street SW  
Washington DC, 20204



Dear Dr. Yetley,

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™ helps balance blood glucose [sugar] levels for health and weight maintenance.

The FDA disclaimer will also appear on the label.

Sincerely,

Katie Ferren  
Marketing Director  
SGTI