



MAR 21 2002

6390 '02 MAR 26 P2:20

Mr. Robert Crayhan
President
Designs for Health
2 North Road
East Windsor, Connecticut 06088

Dear Mr. Crayhan:

This is in response to your letter of February 22, 2002 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)). In your letter, you notified us about a claim you intend to use for your dietary supplement Policosanol and Gugulipid.

The product **Policosanol and Gugulipid** uses the claim "...supports healthy cholesterol levels." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The claim for your product contains no such clarification, however. Therefore, FDA considers it to be an implied claim to prevent coronary heart disease by preventing the development of elevated cholesterol levels or reducing elevated cholesterol.

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, or mitigate a disease. 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

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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, New England District Office, Office of Compliance, HFR-NE240

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR § 101.93

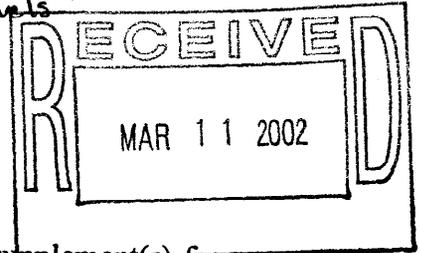
This notification is being filed on behalf of Designs for Health which is the distributor of the product(s) which bear the statements identified in this notification. Its business address is: 2 North Rd. East Windsor CT 06088. This notification is being made pursuant to Section 6 of DSHEA and 21 C.F.R. § 101.93. The dietary supplement product on whose label or labeling the statements appear is Policosanol + Gugulipid

A. The text of each structure-function statement for which notification is now being given is:

(Statement 1): "Supports Healthy Cholesterol Levels"

(Statement 2):

(Statement 3):



B. The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1.	Policosanol and Gugulipid
2.	
3.	

C. The following identifies the brand name of each supplement for which a statement is made: (Complete this section only if the supplement(s) were not identified in Paragraph B.)

<u>Statement Number</u>	<u>Brand Name</u>
1.	
2.	
3.	

I, Robert Crayhan, am authorized to certify this Notification on behalf of Designs for Health. I certify that the information presented and contained in this Notification is complete and accurate, and that Designs for Health has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 2/22/02

By: [Signature]

[Name] Robert Crayhan
[Title] President