



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 20 2000

0197 '00 DEC -7 P3:07

Richard Hau
President
Sanatur Gesellschaft fur Naturprodukte mbH
Georg-Fischer-Stasse 40a
D-78224 Singen
Germany

Dear Mr. Hau:

This is in response to your letter of October 26, 2000 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 Sanatur Gesellschaft fur Naturprodukte mbH, is making the following claim, among others, for the product **Spirulina platensis Hau**:

“...healthy 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 disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggest 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.

Please contact us if you require 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

975-0163

LET 423

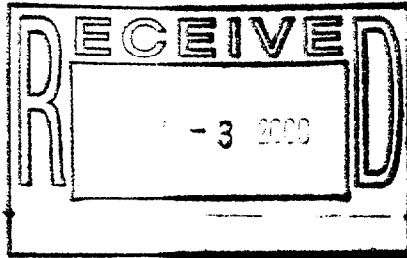
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Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.

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26/10/00

**NOTIFICATION OF STATEMENTS
OF NUTRITIONAL SUPPORT**

This notification is filed pursuant to section 403r(6) of the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. § 343(r)(6).

Namen of dietary supplement	Spirulina platensis Hau
Dietary ingredient	spirulina platensis powder
Statement of nutritional support	supports immune system healthy cholesterol

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statements are truthful and not misleading.

Richard Hau / President