



JAN 29 1997

Dr. Ronald Lane
Chief Executive Officer
NutraGenics
2425 E. Camelback Road, Suite 650
Phoenix, Arizona 85016

Dear Dr. Lane:

This is in response to your letter of December 24, 1996 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statement for your product, Evolve™ with the dietary ingredient Clearesterol™.

Helps lower cholesterol.

This claim does not come within the coverage of section 403(r)(6) of the act. We would point out that section 403(r)(6) of the act 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 prevent, treat, or mitigate heart disease, in that it claims that it "[H]elps lower cholesterol." A product that claims to lower cholesterol, but is not used in the context of dietary management, is a drug within the meaning of section 201(g)(1)(B) of the act, and is subject to regulation under the drug provisions of the act. If you intend to make a claim 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 we may be of further assistance.

Sincerely yours,

James Tanner, Ph.D.
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Los Angeles District Office, Office of Compliance, HFR-PA200
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200