



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

OCT - 8 1998

3520 '98 OCT 13 P2:12

Mr. Gordon M. Walker
Regulatory Counsel
Naturalife
10 Mountain Spring Parkway
Springville, Utah 84663

Dear Mr. Walker:

This is in response to your letter of September 29, 1998 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 Naturalife is making the following claim, among others, for the product "Chasteberry:"

"PMS Support..."

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 a disease, namely premenstrual syndrome (i.e., PMS). 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.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
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, Denver District Office, Office of Compliance, HFR-SW240

975-0163

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (r/f, File)

HFS-450 (r/f, File)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

f/t:HFS-456:rjm:10/7/98:docname:61548.adv:disc32



September 29, 1998

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

RECEIVED
10/6/98

Dear Dr. Kahl:

NaturaLife Corporation wishes to notify the Food and Drug Administration that it has, within the past 30 days, commenced marketing a dietary supplement which bears a statement under Section(r)(6) of the Federal Food, Drug and Cosmetic Act.

The dietary supplement for which the statement is made is Chasteberry. The dietary ingredient that is the subject of the statement is Chasteberry fruit (*vitex agnus castus*) extract. The statement reads as follows:

"PMS Support. More than 200 studies show that NaturaLife Chasteberry extract helps balance a women's monthly cycle."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

The information contained in this notice is complete and accurate and the above statement is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURALIFE CORPORATION

Gordon M. Walker
Regulatory Counsel

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