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OCT - 2 2000

Lisa Conte
CEO and President
Shaman Pharmaceuticals, Inc.
213 East Grand Avenue
South San Francisco, California 94080-4812

Dear Ms. Conte:

This is in response to your letter of August 29, 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 Shaman Pharmaceuticals, Inc. is making the following claim, among others, for the product **Shaman Botanicals Normal Stool Formula**:

"...controls diarrhea without causing constipation."

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, namely diarrhea. 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 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

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, San Francisco District Office, Office of Compliance, HFR-PA140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

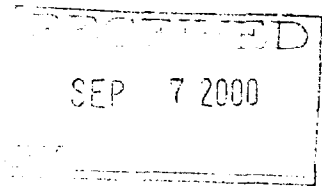
HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Nickerson)

f/t:HFS-811:afp:9/26/00:docname72298.disc1



August 29, 2000

Dr. Robert Moore
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street, S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Moore:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Shaman Pharmaceuticals, Inc. 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 of nutritional support. The supplement for which this statement is made is a standardized extract of *Croton lechleri*. The statements of nutritional support read as follows:

- **NSF-IB controls diarrhea without causing constipation.**
- **Shaman Botanicals Normal Stool Formula is a standardized extract from the sap of the *Croton lechleri* tree that has been used for centuries by shamans (traditional healers) in the Amazon rainforest to relieve diarrhea without causing constipation.**
- **Clinical studies demonstrated that this compound normalizes excess water flow in the intestinal tract and relieves diarrhea, without causing constipation.**

These statements are accompanied by the required disclaimer, which is prominently displayed, on the label.

These statements are based on a body of scientific, clinical and ethnomedical data which, in our judgement, renders these statements truthful, non-misleading and substantiated.

Sincerely,

Lisa Conte
CEO and President

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