

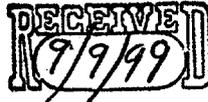


# Shaman

PHARMACEUTICALS, INC.

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August 30, 1999



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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:

- **SB-Normal Stool Formula normalizes water flow in the bowel and promotes normal stool formation.**
- **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 promote normal stool formation.**
- **Clinical studies demonstrated that this compound normalizes excess water flow in the intestinal tract and promotes normal stool formation, 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  
President

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