



JAN 12 1997

Mr. Peter Finkle  
Yerba Prima  
740 Jefferson Avenue  
Ashland, Oregon 97520

Dear Mr. Finkle:

This is in response to your letter of December 20, 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 statements for your products, Colon Care Formula and Colon Care Caps.

The complete fiber formula in Colon Care absorbs and removes toxins from the colon so they do not damage colon walls or get reabsorbed into the bloodstream. Calcium neutralizes toxins in the colon by binding them as insoluble calcium salts, which are then eliminated. FOS selectively promotes the growth of friendly bacteria such as acidophilus and bifidus. They promote better digestion, acidify the colon, and help to keep harmful bacteria and yeast under control.

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 statements that you are making for these products suggest that they are intended to treat or mitigate disease of the colon. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that these products are intended for use as drugs within the meaning of section 201(g)(1)(B) of the act, and that they are 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, Seattle District Office, Office of Compliance, HFR-PA300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

# Yerba Prima<sup>®</sup>

Yerba Prima  
740 Jefferson Avenue  
Ashland, OR 97520  
Phone: 541-488-2228  
Fax: 541-488-2443

Attn: Elizabeth Yetley  
Center for Food Safety  
Food and Drug Administration  
200 C Street SW  
Washington, DC 20204

Dear Ms. Yetley,

## NOTICE OF STATEMENT OF NUTRITIONAL SUPPORT UNDER DSHEA:

Products: Colon Care Formula  
Colon Care Caps

### Statements:

Promotes colon health.\*

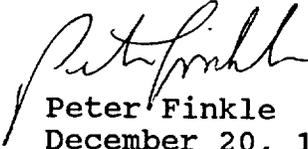
Fiber calcium and FOS synergistically promote colon health.\*  
The complete fiber formula in Colon Care absorbs and removes  
toxins from the colon so they do not damage colon walls or get  
reabsorbed into the bloodstream.\*

Calcium neutralizes toxins in the colon by binding them as  
insoluble calcium salts, which are then eliminated.\*

FOS selectively promotes the growth of friendly bacteria such as  
acidophilus and bifidus. They promote better digestion, acidify  
the colon, and help to keep harmful bacteria and yeast under  
control.\*

\*The "FDA statement" in bold print is also included on the label.

Best regards,

  
Peter Finkle

December 20, 1996

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