



JUL 24 1996

Ms. Janet K. Sperry
Marketing Assistant
Flora, Inc.
P.O. Box 950
Lynden, Washington 98264

Dear Ms. Sperry:

This is in response to your letter of June 6, 1996 making a submission 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 on the label or in the labeling of your product "BioPectin™ Modified Citrus Pectin:"

Modified citrus pectin is a natural complex carbohydrate extracted from a selection of fine citrus fruit pulps. BioPectin™ is absorbed into the bloodstream, where it attaches to undesirable cells, helping your body to eliminate them. This may be particularly helpful for inhibiting the spread of defective prostate cells.

We would point out that section 403(r)(6) of the act makes it 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 "BioPectin™ Modified Citrus Pectin," suggest that this product is intended to treat or mitigate a disease, namely, prostate disease. Therefore, this claim does not qualify as a section 403(r)(6) claim, but rather is subject to regulation under the drug provisions of the act. Thus, it appears that this product is intended for drug use within the meaning of section 201(g)(1)(B) of the act. If you intend to make claims of this

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nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

We hope this information is helpful.

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

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Seattle District Office, Office of Compliance, HFR-PA340
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200