

SEP 24 1996

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

Dear Ms. Sperry:

This is in response to your letter of August 14, 1996 concerning the statement of nutritional support that you are using on your product BioPectin™ Modified Citrus Pectin. Your letter was in response to a letter from the Food and Drug Administration (FDA) dated July 24, 1996. You state that you are making the following statement 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.

Any statement that claims that an ingredient in a product is intended to attach "to undesirable cells, helping your body to eliminate them" and is intended to be "helpful for inhibiting the spread of defective prostate cells" is not a statement permitted under section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), which would describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans. Instead, rather a statement of the type that you make is subject to regulation under the drug provisions of the act. As stated in our previous letter, this statement suggests that this product is intended to prevent, treat, or mitigate prostate disease. Therefore, 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.

Section 403(r)(6)(B) of the act requires that "the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading." However, there is no requirement that the manufacturer share this information with the FDA. Substantiation of a claim is not relevant to making a determination that a claim is intended to affect the structure or function in humans, and is permitted on the label or in the labeling of a dietary supplement under section 403(r)(6) of the act, or that the claim is for an article intended to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases, and therefore, subjects the product to regulation under the drug provisions of the act.

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LET 27

**Page 2 - Ms. Janet Sperry**

**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**

**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**