JUN 18 1997 '97 AUG 12 A10:04

Harunobu Amagase, Ph.D.
Director, Research and Development
Wakunaga of America Co., Ltd.
23501 Madero
Mission Viejo, California 92691-2764

Dear Dr. Amagase:

This is in response to your letter to the Food and Drug Administration (FDA) dated June 6, 1997, responding to our letter of May 22, 1997 to Mr. Mitsuru Takiura, President of Wakunaga of America Co., Ltd.

In a letter dated April 2, 1997, Wakunaga of America Co., Ltd., made a submission to FDA pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), stating that the firm was making the following statements in the labeling of the product "Probiata:"

> Replenishes healthy intestinal flora, avoiding disorders such as diarrhea, constipation and yeast discomfort caused by antibiotic usage.

As we stated in our letter to Mr. Takiura, dated May 22, 1997, these statements evidence that this product is intended for other than food use within the meaning of section 201(g)(1)(B) of the act, in that it is intended to treat, prevent or mitigate "disorders such as diarrhea, constipation and yeast discomfort caused by antibiotic usage." This claim represents the intended use of this product to treat, prevent, or mitigate adverse events associated with use of a drug that is a recognized therapy for a disease, and as such, represents the product for use in the treatment, prevention, or mitigation of a drug-induced disease. As stated in our previous letter, if you intend to make such claims, you should immediately contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855. Since there is no information in your submission that would lead us to change our position in this matter, we do not believe that a meeting at this time would be helpful.

Sincerely yours,

Robert J. Moore, Ph.D.
Senior Regulatory Scientist
Division of Programs and Enforcement Policy
Office of Special Nutritionals

94S-0163

LET 52

cc:
GCF-1 (PDerfler, w/cpy incoming)
HFA-224 (w/incoming)
HFD-314 (JAronson, w/cpy incoming)
HFS-22 (CCO)
HFS-450 (w/cpy incoming, r/f)
HFS-456 (Ross, Moore w/cpy incoming, r/f)
r/d:HFS-456:RJMoore:6/17/97
Intd:GCF-1:PDerfler::6/18/97
f/t:HFS-456:RJMoore:rjm:6/18/97:DocName:amagase.OSN:Disc21

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A Subsidiary of Wakunaga Pharmaceutical Co., Ltd.

VIA FEDERAL EXPRESS

RECEIVED 6/9/97
HFS-456

June 6, 1997

James Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Public Health Service
Food and Drug Administration
Washington, DC 20204

Dear Dr. Tanner:

Thank you for your letter of May 22, 1997 addressed to Mitsuru Takiura regarding our **Probiata** *L.acidophilus* probiotics supplement.

We do not believe that the statements in the labeling of **Probiata** make, or intend to make, a disease claim. Antibiotics are essential to control harmful bacteria in the body. However, antibiotics have the well-documented effect of also killing *Lactobacillus acidophilus* and other friendly bacteria. This effect of antibiotics is not a "disease" but a well documented side effect. For example, a recent article in the Journal of the American Medical Association (March 20, 1996; Vol. 275; No.11) describes the most common side effect of antibiotic usage as Antibiotic Associated Diarrhea.

The addition of probiotics, such as **Probiata,** to the diet may help restore necessary intestinal flora to maintain the normal structure/function of the intestinal tract. We can provide substantial documentation to support this point if you wish.

In that connection, physicians and pharmacists routinely recommend yogurt (because of the acidophilus it contains) to those who have experienced a change in the structure/function of the intestinal tract due to antibiotic use. The dietary supplement **Probiata** is merely a concentrated form of acidophilus that works in a similar manner. **Probiata** and yogurt are two ways to introduce the acidophilus, or friendly bacteria, lost during the course of an antibiotic regimen. Thus, **Probiata** merely helps to maintain the natural condition of the body.

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The structure/function statement made in the labeling recommends use of **Probiata** only for diarrhea, etc. caused by antibiotic usage. There is no reference to, or recommendation of any use of the dietary supplement for diarrhea, etc. caused by any disease.

In summary, we believe that:

1. The statement in the labeling of **Probiata** is designed only to recommend use of **Probiata** as a dietary supplement during and after antibiotic usage to help maintain normal body function.
2. Diarrhea and other conditions associated with use of antibiotics are not diseases. Therefore, **Probiata** does not claim to treat diseases.
3. **Probiata** affects the structure/function of the body, especially the digestive tract, and complies with 403 [r] [6].

We would appreciate the opportunity to discuss this issue further. Perhaps it would be possible to schedule an appointment at your convenience. We feel confident that we can prove **Probiata** to be a safe way to positively impact the structure/function of the body.

Thank you for your kind assistance.

Sincerely,

Harunobu Amagase, Ph.D.
Director, Research and Development

HA:dfh

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June 6, 1997

BY HAND DELIVERY

James T. Tanner, Ph.D.
Acting Director
Division of Programs & Enforcement Policy
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration (HFS-451)
200 C Street, S.W., Room 2804
Washington, D.C. 20204

Dear Dr. Tanner:

Thank you for returning my call this morning and discussing your May 22, 1997, letter addressed to Mr. Mitsuru Takiura concerning the labeling for the product "Probiata."

In our discussion, you confirmed that the direction of the letter to Mr. Takiura personally, without reference to his position as the President of Wakunaga of America Co., Ltd., the manufacturer of the product, was an oversight and that the letter should have been addressed to Mr. Takiura in his official capacity.

If at all possible, we would appreciate your sending a revised letter that addresses Mr. Takiura in his capacity as President of the notifying company, in order to avoid any misunderstanding as to the correct addressee of the letter.

Thank you for your consideration in this matter.

Sincerely,

Paul M. Hyman

Paul M. Hyman

PMH/eam
cc: Mitsuru Takiura, President
Wakunaga of America Co., Ltd.