DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Los Angeles District
1521 West Pico Boulevard
Los Angeles, California 90015-2486
Telephone (213) 252-7583

REGULATORY LETTER

November 3, 1988

Mr. Mas Ohkubo
Executive Vice President
Wakunaga of America Co., Ltd.
23501 Madero Street
Mission Viejo, CA 92691

LA-06-9

Dear Mr. Ohkubo:

This letter is written in reference to the marketing of Yeast-Gard by your organization. Promotional material (labeling) distributed with the product states or suggests that Yeast-Gard is useful in the treatment of vaginal infections caused by yeast.

Because such labeling includes statements which represent and suggest that this article is intended to be used in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body of man, this product is a drug within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act. Further, we are unaware of any substantial scientific evidence which documents that this drug is generally recognized as safe and effective for the treatment of vaginal infections caused by yeast or any other disease condition. The drug is therefore, a new drug within the meaning of Section 201(p). Accordingly, marketing of this drug is a violation of the Federal Food, Drug and Cosmetic Act as follows:

SECTION	BRIEF DESCTIPTION
502(a)	The article of drug is misbranded in that its labeling is false and misleading by representations and suggestions that the article is a homeopathic preparation and that there is substantial scientific evidence to establish that the article is safe and effective for the treatment of vaginal infections caused by yeast.
502(f)(1)	The article of drug is misbranded in that its labeling fails to bear adequate directions for the use in the treatment of vaginal infections caused by yeast for which the article is represented or suggested, and it is not exempt from this requirement under regulation 21 CFR 201.115 since the article is a new drug within the meaning of Section 201(p) and no approval of an application filed pursuant to Section 505(b) is effective for this drug.

The article of drug, Yeast-Gard, is further misbranded in that its labeling does not contain adequate directions for use as this term is defined in 21 CFR 201.5 since the conditions for which it is offered are not amenable to self diagnosis and treatment by the laity; therefore, adequate directions for use cannot be written under which the layman can use this drug safely and for the purposes for which it is intended.

505(a) The article, Yeast-Gard, is a drug within the meaning of Section 201(g) of the Act which may not be introduced or delivered for introduction into interstate commerce under Section 505(a) of the Federal Food, Drug and Cosmetic Act, since it is a new drug within the meaning of Section 201(p) of the Act and no approval of an application filed pursuant to Section 505(b) is effective for such drug.

The violations listed above are not meant to be all inclusive. It is your responsibility as a drug manufacturer and distributor to ensure that all of your products, particularly the Kyolic brand of garlic products, are the subject of approved new drug applications wherever appropriate and that the products are properly labeled for their intended uses.

We request that you reply within ten (10) days of your receipt of this letter stating the action you will take to discontinue the marketing of this drug product. If such corrective action is not promptly undertaken, the Food and Drug Administration is prepared to initiate legal action to enforce the law. The Federal Food, Drug and Cosmetic Act provides for seizure of illegal products or injunction against the manufacturer or distributor of illegal products (21 USC 332 and 334).

Your response should include:

1. An estimate of the quantity of the drug manufactured or received within the past twelve (12) months.

2. An estimate of the size and frequency of shipments made by you in the past twelve (12) months.

3. An estimate of the amount of the drug that is in inventory under your control and your estimate of the amount in distribution channels outside your control.

4. The date of discontinuance in the event that you have already discontinued marketing this drug product.

5. Your intention with respect to the disposition of your inventories and outstanding stocks in trade channels.

Your reply should be directed to:

Mr. Thomas L. Sawyer
Director, Compliance Branch
U.S. Food and Drug Administration
1521 West Pico Blvd.
Los Angeles, CA 90015

This letter has also been issued to: Women's Health Institute, Suite 234, 25422 Trabuco Rd., #105, El Toro, California 92630.

Sincerely,

George J. Gerstenberg
District Director

cc: Ms. Shirley Saito, President
Women's Health Institute
Suite 234, 25422 Trabuco Rd., #105
El Toro, CA 92630

[redacted]