



MAR 13 1998

Food and Drug Administration  
Washington, DC 20204

*Rec'd 3/20/98 jt*

Mitsuru Takiura  
President  
Wakunaga of America Co., Ltd.  
23501 Madero  
Mission Viejo, CA 92691-2764

Dear Mr. Takiura:

This is in response to your letter of July 8, 1997 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Wakunaga of America Co., Ltd. is making the following claim for the product "Kyolic Echinacea:"

"Nutrition for the cold and flu season."

21 U.S.C. 343(r)(6) 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 statement that you are making for this product suggests that it is intended to prevent, treat or mitigate a disease, namely the common cold and influenza. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). The claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. 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.

Please contact us if we may be of further assistance.

Sincerely,

James T. 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, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200  
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

975-0163

LET 144



**KYOLIC®**  
Aged Garlic Extract™

Wakunaga of America Co., Ltd.  
A Subsidiary of Wakunaga Pharmaceutical Co., Ltd.

July 8, 1997

RECEIVED  
JUL - 8 1997

VIA FEDERAL EXPRESS

TEL: 202.401.9636

Office of Special Nutritionals (HFS-455)  
Center for Food Safety and Applied Nutrition  
FOOD AND DRUG ADMINISTRATION  
200 "C" Street, S.W.  
Washington, D.C. 20204

Dear Sir or Madam:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 343(r)(6), this is to notify FDA that our company has begun to include in the labeling of its Dietary Supplement product, **Kyolic® Echinacea**, which contains aged garlic extract (*Allium sativum*) and echinacea extract (*Echinacea angustifolia*), the following statement of nutritional support: Nutrition for the cold and flu season.

Sincerely,

  
Mitsuru Takiura  
President

MT/mat