

KYOLIC®
Aged Garlic Extract™

Wakunaga of America Corp. THE
A Subsidiary of Wakunaga Pharmaceutical Co. Ltd.
NUTRITIONALS, HFS-450

February 10, 1997 FEB 12 P 3:48

RECEIVED
2/11/97
HFS-456

VIA FEDERAL EXPRESS

TEL: 202.401.9636

0019 '97 SEP 19 P1:28

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 **KYO•CHROME®** Dietary Supplement which contains garlic, chromium and niacin, the following statements of nutritional support: "Cholesterol Formula" and "When used as part of a low fat, low cholesterol diet, **KYO•CHROME®** may help reduce cholesterol for people lacking in Chromium and Niacin."

Sincerely,



Mitsuru Takiura
President

MT/mat

975-0162

51100

LET 532