



JUN - 4 1999

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Masaki Aburada, Ph.D.  
General Manager of International Division  
Tsumura & Company  
12-7, Nibancho, Chiyoda-ku  
Tokyo 102-8422  
JAPAN

Dear Dr. Aburada:

This is in response to your letter of May 19, 1999 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 Tsumura & Company is making the following claim for the product **KAKKON-TO Herbal Supplement**:

“Support normal body function during the cold 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 treat, prevent, or mitigate disease, namely, the common cold. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This 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 you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

975-0163

LET 277

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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, San Francisco District Office, Office of Compliance, HFR-PA140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605 (Bowers)

HFV-228 (Benz)

HFV-232 (Brown)

GCF-1 (Dorsey, Barnett)

f/t:HFS-456:rjm:6/4/99:docname:65456.adv:disc38

# TSUMURA & CO.

12-7, Nibancho, Chiyoda-ku, Tokyo 102-8422, Japan

Telephone: 03 3221 0155

Facsimile : 03 3221 0016

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St., S.W.  
Washington, DC 20204  
U.S.A.

May 19, 1999

Dear Sirs,

## Notification of Statement on Dietary Supplement

In accordance with the Code of Federal Regulation revised as of April 1, 1998 §101.93 (a), I, Masaki Aburada, Ph.D. General Manager of International Division of Tsumura & Co., a Japanese corporation, do hereby notify:

(i) The name and address of the manufacturer of the dietary supplement that bears the statement.

Company name: Tsumura & Co.  
Registered address: 4-10, Nihombashi 3-chome, Chuo-ku, Tokyo 103-0027 Japan.  
Head office address: 12-7, Nibancho, Chiyoda-ku, Tokyo 102-8422, Japan.

(ii) The text of the statement that is being made.

Supports normal body function during the cold season.

(iii) The name of the dietary ingredients that are subject of the statement.

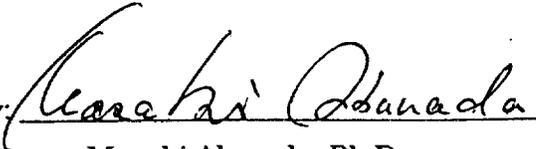
Dried water extract of the following blend of raw herbs;  
Kudzu Root, Jujube Fruit, Ephedra Herb, Licorice Root, Cinnamon Bark, White Peony Root and Ginger Rhizome.

(iv) The name of the dietary supplement including brand name.

Herbal Supplement  
KAKKON-TO

IN WITNESS WHEREOF, I have hereunto set my hand on this 19<sup>th</sup> day of May, 1999.

Yours faithfully,  
Tsumura & Co.

By:   
Masaki Aburada, Ph.D.

General Manager of International Division