



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

FEB 25 2000 1733 '00 FEB 29 P2:11

Masaki Aburada, Ph.D.
General Manager of International Division
Tsumura & Co.
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 & Co. is making the following claim for the product "**Gorei-San-Ryo**:"

"Helps promote normal body function after taking too much drink."

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 diseases, namely alcohol intoxication or adverse health effects associated with excessive alcohol consumption. 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 we may be of further assistance.

Sincerely,

John B. Foret, Ph.D.
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

975-0163

LET 338

Page 2 - Dr. Masaki Aburada

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-800 (r/f, file)

HFS-810 (r/f)

HFS-800 (file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Barnett, Nickerson)

f/t:HFS-456:rjm:2/24/00:docname:65456b.adv:disc45

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.

Helps promote normal body function after taking too much drink.

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

Dried water extract of the following blend of raw herbs;

Alisma Rhizome, Southern Tsangshu Rhizome, Polyporus Sclerotium, Poria Sclerotium and Cinnamon Bark.

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

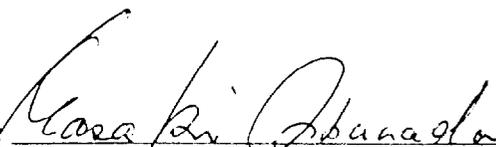
Herbal Supplement

GOREI-SAN-RYO

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

Yours faithfully,

Tsumura & Co.

By 

Masaki Aburada, Ph.D.

General Manager of International Division