



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAY 22 2000 8 28 7 '00 MAY 25 P2:01

Mr Phillip So
President
So's (U.S.A.) Company, Inc.
1043 Cesar E. Chavez Avenue
Los Angeles, California 90033

Dear Mr. So:

This is in response to your letter of May 11, 2000 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 So's (U.S.A.) Company, Inc. is making the following claim, among others, for the product **Fargelin For Piles Herbal Supplement**:

"Fargelin For Piles promotes anal health."

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, including the use of the term "piles" in the product name, suggests that it is intended to treat, prevent, or mitigate a disease, namely hemorrhoids. 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,

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

975-0163

LET 370

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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, Los Angeles District Office, Office of Compliance, HFR-PA240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Barnett, Nickerson)

f/t:HFS-811:rjm:5/18/00:docname:70741.adv:disc47



美國蘇氏藥業有限公司

SO'S (U.S.A.) COMPANY, INC.

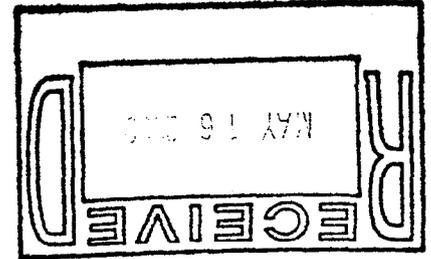
1043 CESAR E. CHAVEZ AVE., LOS ANGELES, CA 90033

TEL: (323)221-8180 FAX: (323)221-2448

WWW.SOSUSA.CO.COM

May 11, 2000

70741



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

RE: Dietary Supplement Statement of Support Notification

To Whom It May Concern:

SO'S (U.S.A.) COMPANY, INC., 1043 Cesar E. Chavez Avenue, Los Angeles, CA 90033, who is the distributor of the following dietary supplement product, intends to make the following statement of support:

"Fargelin For Piles promotes anal health. This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

This claim is being made for:

Fargelin For Piles Herbal Supplement

which is contained in:

Fargelin For Piles Herbal Supplement

This submission is being made in compliance with 21 CFR § 101.93.

The undersigned is an authorized representative of the SO'S (U.S.A.) COMPANY, INC. and certifies that the information contained in this notice is complete and accurate, and that SO'S (U.S.A.) COMPANY, INC. has substantiation that the above statement is truthful and not misleading.

Phillip So
President