



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

SEP 28 1999

1748 50 00 00 00

S. W. Flowers
Chief Executive Officer
ShmsHrs, Inc.
PO Box 539
Maplewood, New Jersey 07040

Dear Mr. Flowers:

This is in response to your letter, received on September 20, 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 ShmsHrs, Inc. is making the following statement for its product "Relieve":

"For itching, burning, and heat disorders"

"For damp heat problems characterized by symptoms like burning, itching, heat, and discharge. Especially useful for problems in and around the genitalia, urinary tract, and rectum."

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 statements that you are making for this product suggests that it is intended to prevent, treat, cure, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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.

'Procedural requirements for the submission required by 21 U.S.C. 343(r)(6) are set forth in the agency's regulations at 21 CFR 101.93(a); a copy is enclosed for your information.

975-0163

LET 299

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Please contact us if we may be of 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

Enclosure

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, New Jersey District Office, Office of Compliance, HFR-MA340

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (File)

HFS-450 (file, r/f)

HFD-3 10 (B Williams)

HFD-3 14 (Aronson)

HFS-605 (Bowers)

GCF- 1 (Nickerson, Dorsey, Barnett)

HFV-228 (SBenz)

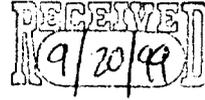
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ShmsHrs, Inc.

PO Box 539

Maplewood, NJ 07040



To: Food and Drug Administration /HFE-88, Rockville MD 20857

From: ShmsHrs Corp./ S.W. Flowers, Chief Executive Officer

A handwritten signature in black ink, appearing to be "S.W. Flowers", written over the "From:" line.

Re: New Dietary Supplement RELIEVE

In accordance with the "FDA Guide to Dietary Supplements" we are informing you of the release of our herbal product with the following structure function claim:

"For itching, burning, and heat disorders"

"**F**or damp heat problems characterized by symptoms like burning, itching, heat, and discharge. Especially useful for problems in and around the genitalia, urinary tract, and rectum."

We have applied your mandatory disclaimer to the label:

"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."

"Consult your physician before using."