



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 18 1998 3381 '98 NOV 25 P2:23

Ms. Lynda Sadler
President
Traditional Medicines
4515 Ross Road
Sebastopol, California 95472-2250

Dear Ms. Sadler:

This is in response to your letter of November 9, 1998 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 Traditional Medicines is marketing a product named "PMS Tea Herbal Dietary Supplement."

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, namely the product name "PMS Tea," suggests that this product is intended to treat, prevent, cure, or mitigate a disease, namely premenstrual syndrome (i.e., PMS). 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,

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

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

975-0163

LET 240

Page 2 - Ms. Lynda Sadler

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (r/f, File)

HFS-450 (r/f, File)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Dorsey)

f/t:HFS-456:rjm:11/17/98:docname:62279.adv:disc33

Traditional Medicinals®
FIRST IN MEDICINAL HERB TEAS.

9. November 1998

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20204

11/16/98

To whom it may concern,

Pursuant to 21 CFR 101.93 (a) (2), Traditional Medicinals, Inc., 4515 Ross Road, Sebastopol, California 95472 hereby notifies the FDA that it is making the following statement covered by the referenced regulation for its;

PMS Tea™ Herbal Dietary Supplement containing a proprietary herbal blend of roasted dandelion root, roasted carob pod, roasted chicory root, parsley leaf, oatstraw herb, nettle leaf, chickweed herb, uva ursi leaf, cornsilk style and stigma and cramp bark: **“Promotes a Healthy Pre-Menstrual Cycle”**.

The undersigned certifies that the information contained in this notice is complete and accurate and that Traditional Medicinals, Inc. has substantiation that the statement is truthful and not misleading.

Very truly yours,



Lynda Sadler

President

Also see docket 975-0163



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