



1040 '01 APR 13 P3:21

MAR 30 2001

Ms. Lynda Sadler
President
Traditional Medicinals, Inc.
45 15 Ross Road
Sebastopol, California 95472

Dear Ms. Sadler:

This is in response to your letters of March 16, 2001 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 Medicinals, Inc. is making the following claim for the following products:

Cold Care PM[®]

“Promotes Relaxed Nighttime Breathing.”

Gypsy Cold Care'

“Supports Clear Breathing. . . ”

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 these products, along with the names of the products (i.e., Cold Care PM and Gypsy Cold Care), suggest that they are intended to treat, prevent, cure, or mitigate a disease, namely the common cold. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C.

321(g)(1)(B), and that they are 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-3 10, 7520 Standish Place, Rockville, Maryland 20855.

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Please contact us if we may be of 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

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

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cc:

HFA-224

HFA-305 (docket 978-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-8 10 (Foret)

HFS-8 11 (Moore, w/original incoming)

HFD-40 (Behrman)

HFD-310

HFD-3 14 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF- 1 (Nickerson)

r/d:HFS-811:RMoore:3/27/01

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16. March 2001

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

To whom it may concern,

Pursuant to 21 CFR 101.93 (a) (2), Traditional Medicinals, Inc., 45 15 Ross Road, Sebastopol, California 95472 hereby notifies the FDA that it is making the following statement covered by the referenced regulation for its;

Cold **Care PM**® Herbal Dietary Supplement containing a proprietary herbal blend of European Linden flower (Flos Tiliae Ph.Eur.), European Elder flower (Flos Sambuci Ph.Eur.), Peppermint leaf (Folium Menthae Piperitae Ph.Eur.), Yarrow herb (Herba Millefolii Ph.Eur.), Eucalyptus leaf (Folium Eucalypti Ph.Eur), German Chamomile flower (Flos Matricariae Ph.Eur.), Passionflower herb (Herba Passiflorae DAB), Licorice root (Radix Liquiritiae Ph.Eur.): "Promotes Relaxed Nighttime Breathing."

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

16. March 2001

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

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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;

Gypsy Cold Care® Herbal Dietary Supplement containing a proprietary herbal blend of European Elder flower (Flos Sambuci Ph.Eur.), Yarrow herb (Herba Millefolii Ph.Eur.), Peppermint leaf (Folium Menthae Piperitae Ph.Eur.), Hyssop herb (Herba Hyssopi BHP), Rose hip (Pseudofructus Rosae DAB), Chinese Cinnamon bark (Cortex Cinnamomi Cassiae Ph.PRC), Safflower petal (Flos Carthami Ph.PRC), Ginger rhizome (Rhizoma Zingiberis Ph.PRC), Clove flower bud (Flos Caryophylli Ph.PRC), Licorice root dry native extract (Extractum Glycyrrhizae Ph.PRC): "Supports Clear Breathing — Regulates Body Temperature."

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