



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

SEP - 4 1997

3/24/98

Dr. Sheldon A. Schooler
Physician's Choice Herbal Products
Woodland Farm Ltd.
798 Spring Road
Marathon, Wisconsin 54448-9986

Dear Dr. Schooler:

This is in response to your letter of May 28, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that Woodland Farm, Ltd. is making claims for the products Physician's Choice Rejuvenation and Physician's Choice Woman's.

Rejuvenation

Can Help
Blood Sugar
Immune System
Blood Pressure
Vigor
Graying of Hair
Liver Function

Woman's

Can Help
PMS
Menopause
Mood
Agitation
Constipation

Section 403(r)(6) of the act 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 suggest that they are intended to treat, prevent, or mitigate diseases, namely diabetes or abnormal blood sugar levels, hypertension, PMS, and constipation. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that these product are intended for use as drugs within the meaning of section 201(g)(1)(B) of the

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Page 2 - Mr. Sheldon A. Schooler

act 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-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting 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, Minneapolis District Office, Office of Compliance, HFR-MW340
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

cc:

HFA-224 (w/incoming)
HFS-22 (CCO, KCarson)
HFS-456 (r/f, Miles, Moore)
HFS-450 (r/f)
HFD-304 (Aronson)
HFS-600 (Reynolds)
r/d: C:\miles:7/1/97:C:\Miles\suppl\52874
f/t:R\Moore:8/27/97:52874.adv:disc22

IN THE UNITED STATES
FOOD AND DRUG ADMINISTRATION
OFFICE OF SPECIAL NUTRITIONALS

Subject: Notification, Statement of Nutritional Support, as provided
for in section 403 (r) (6) §101.93 et al.

Notification Mailing Date (Certified Mail): 5/28/97

Distributor: Woodland Farm, Ltd.
798 Spring Rd.
Marathon, Wisconsin 54448

Product Brand Name: Physician's Choice Rejuvenation

Dietary Ingredients: Ginseng, Astragalus, and Foti

Statement(s) Attributable to Ingredient: Ginseng-Blood Sugar Metabolism,
Immune System, Vigor, and Liver Function; Astragalus-Blood Pressure and Liver
function; Foti-vigor and Hair Graying.

Date of First Use In Commerce: 5/13/97

Actual Label Attached Below:

MY SUGGESTED DOSAGE: One capsule morning and evening with meals. Store in cool, dry place.

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.

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© 1997 Woodland Farm, Ltd.
Physician's Choice Quality
the price is in the amount.
Freshness Guar. to:
LOT NO

Physician's Choice™
Rejuvenation
Herbal Dietary Supplement

Developed for you by
SHELDON A. SCHOOLER, M.D.
325 mg 60 capsules

Can Help
Blood Sugar*
Immune System*
Blood Pressure*
Vigor*
Graying of Hair*
Liver Function*

This product contains the following carefully selected herbs:
Choice Wisconsin Ginseng,
Astragalus and Foti.
No additives.
No preservatives.
DO NOT USE IF LABILE,
INSULIN DEPENDENT, DIABETIC

Prepared for
Sheldon A. Schooler, M.D.
Woodland Farm, Ltd.
798 Spring Road
Marathon, WI 54448 U.S.A.

As per §101.93 (c), the undersigned certifies that the information contained in this notice is complete and accurate, and that the notifying firm has reasonable substantiation that the statement is truthful and not misleading.


Sheldon A. Schooler, M.D., President

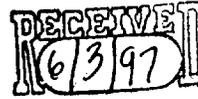
Notification receipt date, _____
Office of Special Nutritionals _____

WOODLAND FARM LTD

798 Spring Road
Marathon, WI 54448-9986

May 28, 1997

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



To Whom It May Concern:

Please find enclosed the document for notification related to a statement of nutritional support under section 403 (r) 6 §101.93 et al. Although the regulation provides for the elements of the notification, it does not provide for the format. Enclosed is my proposal. It is simple and concise.

We are currently in the process of redesigning all of our materials to take advantage of section 403 (r) §101.93 et al. to better inform the consumer. If any elements of the proposed label are objectionable, please notify us within 30 days of the specific objection and the specific reason(s), so that we can make the appropriate adjustments.

Reasonable substantiation has been established related to benefits and especially safety, before any of my products are marketed. It is my policy to personally review the world-wide medical research literature as a part of product development. Having been involved in biochemical medical research in the past, I feel I am reasonably qualified to evaluate the quality and accuracy of the literature I review. It is my purpose to provide beneficial, safe products of the best possible quality to the consumer. I, or members of my immediate family, use my products on a regular basis, and have done so for a number of years.

Sincerely,

A handwritten signature in black ink, appearing to read "Sheldon A. Schooler", written over a horizontal line.

Sheldon A. Schooler, M.D.
Physician's Choice Herbal Products

P.S. This is the third and fourth of six product notices to be sent.

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