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JUL 13 2005

Mr. Michael Friedman
Formulator
WTSmed, Inc.
68 E. State Street, #1
Montpelier, Vermont 05602

Dear Mr. Friedman:

This is in response to your letter (undated) 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 letter states that the following statements will be made for the following products:

ChoLess	Supports healthy cholesterol levels
HTN 180	Promotes healthy blood pressure levels
GlucoBalance	Supports healthy blood sugar levels

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood glucose levels and blood pressure; that is, claims that do not establish that the claims are about blood glucose levels or blood pressure levels that are already within normal limits implies that the product is intended to treat elevated blood glucose (diabetes) or blood pressure (hypertension), which are diseases. Therefore, because the claims you are making for these products represent that the products are intended to affect blood glucose, blood cholesterol, and blood pressure but do not also include a statement about them being intended to affect blood glucose, blood cholesterol, and blood pressure that are already in the normal ranges, they are implied disease claims.

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 suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not

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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-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

We also note that your notification is unsigned and does not contain the certification required under 21 CFR 101.93. 21 CFR 93(a)(3) requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) and this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. Your submissions do not meet this requirement in that the notices do not contain the signature of a responsible individual nor does it certify that the firm is in compliance with the requirements of the Act and the regulation. Therefore, your firm has not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit notifications in accordance with the requirements in 21 CFR 101.93(a). The failure to submit a valid notice as required by the Act and the agency's regulation may subject the products that are the subject of the notification to regulation under the drug provisions of the Act.

Please contact us if we may be of further assistance.

Sincerely yours,


for

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs
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-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, New England District Office, Office of Compliance, HFR-NE240

WTSMED, INC.

Division of Compliance and Enforcement/ONPLDS
Center for Food Safety and Applied Nutrition
Food and Drug Administration
HFS-810
5100 Paint Branch Parkway
College Park, Maryland 20740

JUN 21 2005

Dear Sir or Madam:

This letter is to provide notice, within 30 days of marketing, of product names. These products are herbal, mineral, and hormonal dietary supplements in either liquid, liquid phyto-cap, or encapsulated format. The following is a list of the names and structure function claims:

Adaptogen: Supports adrenal glands
Adaptogen Plus: Supports adrenal glands
Adaptogen Plus II: Supports adrenal glands
RespiraCare: Promotes healthy respiratory function
CardiaCare: Cardiovascular support
CardiaCare Plus: Cardiovascular support
ChoLess: Supports healthy cholesterol levels
DiabCare: Supports healthy blood sugar metabolism
FibroCare: Support for chronic muscle tension
Healthy Foundation: Promotes optimum health
HTN 180: Promotes healthy blood pressure levels
GlucoBalance: Supports healthy blood sugar levels
MigraCare: Support during Stress and Tension
ThyroCare: Supports the thyroid gland
ThyroCalm: Supports balanced thyroid function
UT Formula: Promotes urinary tract health

We have selected the names and structure and function claims to not make or imply a disease claim and meet the requirements of 21 U.S.C. 343(r)(6). Please call me at 802-223-6401 if you need additional information or have any questions.

With kind regards,

Michael Friedman
Formulator, WTSmed

2005-3813

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(802) 223-6401 PHONE
(916) 404-6798 FAX

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