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OCT 15 2003

Ms. Therese P. Cerny
Owner
Herbal Source
6618 Saloma Avenue
Van Nuys, California 91405

Dear Ms. Cerny:

This is in response to your letters of September 25, 2003 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 letters state that the following statements will made for the following products:

Nutri-Lin	Promotes Healthy Blood Sugar Levels
Nutri-Chol	Promotes Healthy Cholesterol Levels
Nutri-Ban	Promotes Healthy Blood Sugar Levels; Promotes Healthy Blood Pressure

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, a claim that does not establish that the claims are about blood glucose levels or blood pressure that is 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

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suggest that they are intended to treat, prevent, or mitigate diseases. 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-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

You also submitted a letter that states you intend to market a product named "Nutri-Derm" that is intended for use as an "Anti-Fungal Lotion For The Skin." This product does not appear to meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, can not be marketed as a dietary supplement. We explain the basis for our opinion below.

The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(i) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the diet, and are labeled as a dietary supplement.

An article that is applied externally to the skin as a lotion is not "intended for ingestion." As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product "intended for ingestion." The term "ingestion" has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff'd, 72 F.3d 285 (2d Cir. 1995), which states:

The ordinary and plain meaning of the term "ingestion" means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman's Medical Dictionary (4th Lawyer's Ed. 1976) (defining ingestion as the "introduction of food and drink into the stomach."); Webster's Third New International Dictionary (1976) (defining ingestion as "the taking of material (as food) into the digestive system.")...

The interpretation of the term "ingestion" to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(i) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(i) "only if it is

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formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure." This elaboration of "liquid form" also denotes ingestion by swallowing the fluid.

Therefore, because the term "ingestion" means introduced into the gastrointestinal tract, products that are intended to be applied externally to the skin are not subject to regulation as dietary supplements because they are not "intended for ingestion." Moreover, your product is represented for use as an anti-fungal lotion. This claim suggests that this product is intended to treat, prevent, or mitigate disease, namely, fungal skin diseases. 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

Please contact us if we may be of further assistance.

Sincerely yours,



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-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93**

OCT - 1 2003

This notification is being filed on behalf of Herbal Source which is the Owner of the product(s) which bear the statements identified in this notification. Its business address is: 6618 Saloma Ave. Van Nuys CA 91405. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appears is Nutri-Derm.

The text of each structure-function statement for which notification is now being given is:

- (Statement 1): Anti-Fungal Lotion For The SKin
 (Statement 2):
 (Statement 3):

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1. 1	<u>AKapulko (leaf)</u>
2.	
3.	

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Names</u>	<u>Label or Labeling</u>
1. 1	<u>Nutri-Derm</u>	<u>Nutri-Derm</u>
2.		
3.		

I, Therese P. Cerny, am authorized to certify this Notification on behalf of Herbal Source. I certify that the information presented and contained in this Notification is complete and accurate, and that Herbal Source has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: Sept. 25, ~~199~~ 2003 By: [Signature], Owner
 [Name]
 [Title]

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93

OCT - 1 2003

This notification is being filed on behalf of Herbal Source which is the Nutri-Chol of the product(s) which bear the statements identified in this notification. Its business address is: 6618 Saloma Ave. Van Nuys CA 91405. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appears is Nutri-Chol.

The text of each structure-function statement for which notification is now being given is:

- (Statement 1): Promotes Healthy Cholesterol Levels
- (Statement 2):
- (Statement 3):

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1. <u>1</u>	<u>Garlic</u>
2.	
3.	

The following identifies the brand name of each supplement for which a statement is made:

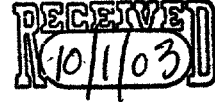
<u>Statement Number</u>	<u>Brand Names</u>	<u>Label or Labeling</u>
1. <u>1</u>	<u>Nutri-Chol</u>	<u>Nutri-Chol</u>
2.		
3.		

I, Therese P. Cerny, am authorized to certify this Notification on behalf of Herbal Source. I certify that the information presented and contained in this Notification is complete and accurate, and that Herbal Source has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: Sept. 25, ~~1999~~ 2003 By: [Signature], Owner
[Name]
[Title]

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NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93



This notification is being filed on behalf of Herbal Source which is the owner of the product(s) which bear the statements identified in this notification. Its business address is: 6618 Saloma Ave. Van Nuys CA 91405. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appears is Nutri-Lin.

The text of each structure-function statement for which notification is now being given is:

- (Statement 1): Promotes Healthy Blood Sugar Levels
- (Statement 2):
- (Statement 3):

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1. <u>1</u>	<u>Bitter Melon (leaf)</u>
2.	
3.	

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Names</u>	<u>Label or Labeling</u>
1. <u>1</u>	<u>Nutri-Lin</u>	<u>Nutri-Lin</u>
2.		
3.		

I, Therese P. Cerny, am authorized to certify this Notification on behalf of Herbal Source. I certify that the information presented and contained in this Notification is complete and accurate, and that Herbal Source has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: Sept. 25, ~~1999~~ 2003 By: [Signature], owner
[Name]
[Title]

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**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 CFR §101.93**

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This notification is being filed on behalf of Herbal Source which is the owner of the product(s) which bear the statements identified in this notification. Its business address is: 6618 Saloma Ave. Van Nuys CA 91405. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appears is Nutri-Ban.

The text of each structure-function statement for which notification is now being given is:

- (Statement 1): Promotes Healthy Blood Sugar Levels
- (Statement 2): Promotes Healthy Blood Pressure
- (Statement 3):

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1. 1	Banaba (leaf)
2. 2	Banaba (leaf)
3.	

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Names</u>	<u>Label or Labeling</u>
1. 1	Nutri-Ban	Nutri-Ban
2. 2	Nutri-Ban	Nutri-Ban
3.		

I, Therese P. Cerny, am authorized to certify this Notification on behalf of Herbal Source. I certify that the information presented and contained in this Notification is complete and accurate, and that Herbal Source has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: Sept. 25, ~~199~~ 2003 By: Therese P. Cerny, owner
 [Name]
 [Title]

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