



NOV 24 2003 4 54 9 PM JAN -7 21 48

Mr. Jim Caras
Chief Executive Officer
Health Direct
16400 Pacific Coast Highway
Suite 215
Huntington Beach, California 92649

Dear Mr. Caras:

This is in response to your letters of September 30, 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 product **Carb Cheater** will use the claim "Supports the maintenance of normal blood sugar and cholesterol 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 sugar levels; that is, a claim that does not establish that the claims are about blood sugar levels that are already within normal limits implies that the product is intended to treat elevated blood sugar levels (diabetes), which is a disease. Therefore, because the claims you are making for this product represent that the product is intended to affect blood cholesterol and blood sugar but does not also include a statement about it being intended to affect blood cholesterol and blood sugar that are already in the normal ranges, it is an implied disease claim.

You also state that the product **Sculpt n' Cleanse - Colon Cleansing Formula** will use the claim "relieving constipation." In FDA's final rule on structure/function claims for dietary supplements, the agency stated that claims to relieve "occasional" constipation could be acceptable structure/function claims, depending on context. See 65 FR 1000, 1015, 1022 (2000). However the claim you are making for your product is not qualified such that it does not represent the product for use to treat or prevent chronic constipation, which is a disease. Therefore, your claim is an implied disease claim.

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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 such as hypertension, heart disease, and injuries. 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.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal line extending to the right.

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

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cc:

all w/copy of incoming

HFA-224

HFA-305 (docket 97S-0163) 

HFS-800 (file)

HFS-810 (file)

HFS-811 (Moore w/original incoming)

HFD-40 (Behrman)

HFD-310

HFD-314

HFS-607

HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:rjm:10/8/03:docname:86395.adv:disc80

September 30, 2003

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

Re: Statement for Dietary Supplement

Dear Sir or Madam:

This letter is submitted as required by Section 406(r)(6) of the Food, Drug & Cosmetic Act (FDC Act) for the purpose of notifying the Food and Drug Administration (FDA) of certain statements being made in connection with the sale of dietary supplement products marketed by this company.

The product name and the dietary ingredients for which certain statements are being made are as follows:

Sculpt n' Cleanse – Colon Cleansing Formula

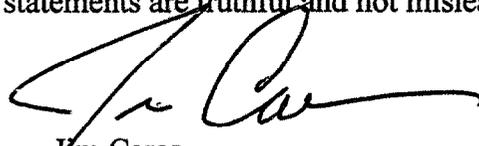
Proprietary Blend 900mg

Cascara sagrada (bark), Senna (pod), Psyllium (seed), Turkey Rhubarb (*Rheum officianale* – root), Slippery Elm (bark), Barberry (*Berberis vulgaris* – root), and Aloe Ferox (Cape Aloe - leaf)

The text of the statements that are being made for the above product is listed below:

First step in weight management, body shaping and digestive health, colon cleansing may be beneficial for weight loss, increasing energy, relieving bloating, flattening the waistline, promoting regularity, relieving constipation, improving skin appearance.

As Chief Executive Officer for Health Direct (HD Nutrition, Inc.), I certify that the information contained in this notification is complete and accurate and that Health Direct (HD Nutrition, Inc.) has substantiation that the above statements are truthful and not misleading.



Jim Caras
Chief Executive Officer
Health Direct (HD Nutrition, Inc.)

86395

September 30, 2003

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

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The product name and the dietary ingredients for which certain statements are being made are as follows:

Carb Cheater

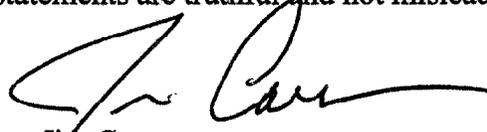
Chromium Amino Acid Chelate 100 mcg
Proprietary Starch and Sugar Carbohydrate Neutralizing Blend 1,275 mg
Phase 2 Brand Bean Extract (*Phaseolus vulgaris*)
Gymnema Sylvestre Extract (25% gymnemic acids)
Fenugreek Seed Extract (FenuLife® - 85% Hydrocolloids)
Proprietary Blood Sugar and Insulin Balancing Blend 141mg
Alpha Lipoic Acid
Green Tea Leaf Extract (*Camellia sinensis*) 50% Polyphenols,
30% Catechins
Glucosol™ (Banaba Leaf Extract – *Lagerstroemia speciosa*)
Vanadium 19% (Vanadyl Sulfate)
Proprietary Herbal Energy Blend 115 mg
Panax Ginseng P.E. (Ginsenoside – 80%)
Bee Pollen Powder
Royal Jelly 3X
Eleuthero Root (0.8% Eleutherosides)

86395

The text of the statements that are being made for the above product is listed below:

Supports weight loss; Supports the maintenance of normal blood sugar and cholesterol levels.

As Chief Executive Officer for Health Direct (HD Nutrition, Inc.), I certify that the information contained in this notification is complete and accurate and that Health Direct (HD Nutrition, Inc.) has substantiation that the above statements are truthful and not misleading.

A handwritten signature in black ink, appearing to read "Jim Caras", written in a cursive style.

Jim Caras
Chief Executive Officer
Health Direct (HD Nutrition, Inc.)