DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUN 29 2001

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Michael D. Bernstein, Esq.
Arent Fox Kintner Potkin & Kahn, PLLC
1050 Connecticut Avenue, N.W.
Washington, DC 20036-5339

Dear Mr. Bernstein:

This is in response to your letter to the Food and Drug Administration (FDA) dated June 6, 2001 on behalf of Amrita Veda, South Fallsburg, New York. Your letter is in response to our letter to Amrita Veda dated April 20, 2001 concerning claims that the firm had notified the agency about pursuant to 21 U.S.C. 343(r)(6). In your letter, you assert that the claim that was subject of our letter, namely, "supports healthy blood sugar levels," is an appropriate structure or function claim that may be made for dietary supplements pursuant to pursuant to 21 U.S.C. 343(r)(6).

In our April 20, 2001 letter, we stated that the claim "supports healthy blood sugar levels" would not be an appropriate structure/function claim under 21 U.S.C. 343(r)(6). In the preamble to the January 6, 2000 final rule (see 65 FR 1000), FDA stated that health maintenance claims that do not imply disease treatment or prevention would be acceptable structure function claims. We stated that if the health maintenance claim did not use terms that are so closely identified with a specific disease or that so clearly referred to a particular at-risk population, we believed that such a claim could be a structure/function claim under 21 U.S.C. 343(r)(6) (see discussion at 65 FR 1018).

You stated in your letter that you believe that the claim "supports healthy blood sugar levels" is an appropriate structure/function claim that does not imply disease treatment, prevention, or mitigation because we stated in the preamble to the final rule that a claim such as "use as part of your diet to help maintain a healthy blood sugar level" would be an acceptable structure/function claim. You further stated that is no material difference between the claim FDA identified in the preamble and the claim that Amrita Veda submitted its notification for. We disagree. We believe that any claim that a product is intended to maintain normal blood glucose levels is an implied disease claim. This conclusion is based on the fact that a claim about external intervention to affect blood glucose levels is implicitly a claim to correct a defect in blood glucose levels because it is not necessary to improve, modify, or otherwise affect blood glucose unless it is impaired.

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However, a claim that a product is important or plays a role in the maintenance or regulation of blood glucose that is already normal or within normal limits could be an appropriate structure/function claim, depending on the context. As we discussed in the preamble to the final rule, the context in which a particular claim is made is important in determining whether a claim may be a disease claim or a structure/function claim. Consequently, if the context of a claim about a product intended to affect blood glucose clearly and unambiguously makes clear that the product is not intended to have an affect on abnormal blood glucose (for example, the claim in the preamble of the January 6, 2000 final rule which you cited in your letter), then such a claim may be an acceptable structure/function claims under 21 U.S.C. 343(r)(6). But, the claim that your client submitted its notification for contains no such context (in the example cited in the preamble, the reference to "use as part of your diet" adds the appropriate context) and, consequently, we do not agree that it is an acceptable structure/function claim under 21 U.S.C. 343(r)(6).

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, New York District Office, Compliance Branch, HFR-NE140

cc:
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (file, r/f)
HFS-810 (Foret)
HFS-811 (file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-607 (Bayne-Lisby)
HFV-228 (Betz)
GCF-1 (Nickerson)
f/t:rjm:HFS-811:6/25/01:76440.adv:disc58

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June 6, 2001

Mr. John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
HFS-810
U.S. Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

RE: May 15, 2001 Courtesy Letter to Amrita Veda

Dear Mr. Foret:

As you know, we represent Amrita Veda of South Fallsburg, N.Y. On May 15, 2001, the FDA sent us the enclosed courtesy letter, objecting to a structure/function claim filed by Amrita Veda on April 20 for the dietary supplements Madhunil and Madhuyog. In the letter, the FDA objects to the claim, "Supports Healthy Blood Sugar Level."

Given that this claim is nearly identical to one approved in the preamble to FDA's Final Rule on structure/function claims for dietary supplements, 65 Fed. Reg. 1000 (January 6, 2000), Amrita Veda is somewhat surprised and puzzled by your letter. In the preamble to the Final Rule, the FDA addressed a comment which asserted that the claim, "use as part of your diet when taking insulin to help maintain a healthy blood sugar level," is an allowable structure/function claim. In response, the Agency stated:

> A general statement that a dietary supplement provides nutritional support would be an acceptable structure /function claim, provided that the statement does not suggest the supplement is intended to augment or have the same purpose as a specific drug, drug action, or therapy for a disease. In the example, if the statement were changed to "use as part of your diet to help maintain a healthy blood sugar level," the claim would be considered acceptable. Deleting the reference to the drug, insulin, would remove the implication that the dietary supplement is used to augment the insulin to treat, mitigate, prevent, or cure diabetes.

65 Fed. Reg. at 1028 (emphasis added).

There is no material difference between the claim FDA approved in the quoted preamble language, and that filed for our client's product. Because Amrita Veda's claim makes no mention of any disease or drug, the claim cannot possibly be read to imply anything different from the

claim that FDA endorsed and approved in the above-quoted preamble language, and therefore, must be an allowable structure/function claim.

Moreover, we believe the FDA is required by its own regulations to follow this preamble language. Pursuant to 21 C.F.R. §10.85, a statement of policy or interpretation made by the Agency in a regulatory preamble constitutes an advisory opinion of the Agency, and remains binding on the Agency, as described in detail in that regulation, unless and until the statement is "amended or revoked." That regulation further states that an advisory opinion must be amended or revoked in the same manner it was established, in this case, by notice and comment rulemaking.

Unless we hear back from you to the contrary, we assume this claim is consistent with the preamble statement and that it therefore meets the requirements of section 403(r)(6) of the Federal Food Drug and Cosmetic Act.

Sincerely,

Michael D. Bernstein

Counsel for Amrita Veda

Enclosure

cc: Avi Farzan, President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAY 15 2001

Michael D. Bernstein, Esq.
Arent Fox Kintner Plotkin & Kahn, PLLC
1050 Connecticut Avenue, NW
Washington, DC 20036-5339

Dear Mr. Bernstein:

This is in response to your letter of April 20, 2001, on behalf of Amrita Veda, 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 Amrita Veda is making the following claim for the products **Madhunil** and **Madhuyog**:

"Supports Healthy Blood Sugar Level."

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 statement that you are making for these products suggests that they are intended to treat, prevent, cure, or mitigate disease, namely, disorders of blood glucose levels. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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, 7520 Standish Place, Rockville, Maryland 20855.

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

Copy:
Mr. Avi Farzan
President
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PO Box 430
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South Fallsburg, New York 12779

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, New York District Office, Office of Compliance, HFR-NE140