



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

MAY 15 2001  
7900 '01 JUN 11 P2:05

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

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Page 2 - Mr. Michael Bernstein

Copy:

Mr. Avi Farzan

President

Amrita Veda

PO Box 430

Lake Street

South Fallsburg, New York 12779

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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

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

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HFS-800 (r/f, file)

HFS-810 (Foret)

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:rjm:5/7/01:docname:75609.adv:disc57

75609

**Michael D. Bernstein**  
202/857-8922  
bernstem@arentfox.com

April 20, 2001

VIA HAND DELIVERY

Office of Nutritional Products, Labeling, and  
Dietary Supplements, (HFS 800)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
200 C Street, S.W.  
Washington, D.C. 20204

RECEIVED  
BY: APR 20 2001

RE: Dietary Supplement Notifications for Amrita Veda

Dear Sir or Madam:

On behalf of our client, Amrita Veda, we are filing the enclosed Notification of Statements of Nutritional Support. Pursuant to the applicable regulations, an original and two copies are attached.

Thank you for your kind attention.

Sincerely,



Michael D. Bernstein

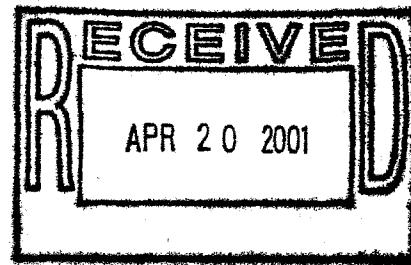
Enclosure

cc: Avi Farzan (w/enclosure)

Amrita Veda  
P.O. Box 430  
Lake Street  
South Fallsburg, NY 12779

April 20, 2001

Office of Nutritional Products, Labeling,  
and Dietary Supplements (HFS-800)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, S.W.  
Washington, D.C. 20204



**NOTIFICATION OF STATEMENTS  
OF NUTRITIONAL SUPPORT**

Dear Sir or Madam:

In accordance with § 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, and pursuant to 21 C.F.R. § 101.93, we hereby provide the following notice with regard to the marketing of the Dietary Supplements described below:

Distributor: Amrita Veda, P.O. Box 430, Lake Street, South Fallsburg, New York 12779.

Brand Name: Ayushakti

1. Name of Supplement : Aamna (proprietary blend).  
Statement of Nutritional Support: Supports Healthy Digestion.
2. Name of Supplement : Amrutadi (proprietary blend).  
Statement of Nutritional Support: For Occasional Constipation.
3. Name of Supplement : Amrutras (proprietary blend).  
Statement of Nutritional Support: Metabolic Formula.

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4. Name of Supplement : Arshna (proprietary blend).  
Statement of Nutritional Support: For Occasional Constipation.

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5. Name of Supplement : Astisandhan (proprietary blend).  
Statement of Nutritional Support: Bone Support.
6. Name of Supplement : Ayurcid (proprietary blend).  
Statement of Nutritional Support: Digestive support.
7. Name of Supplement : Chaitanya (proprietary blend).  
Statement of Nutritional Support: Male System Support.
8. Name of Supplement : Dhatuvaradhak (proprietary blend).  
Statement of Nutritional Support: Rejuvenation Formula.
9. Name of Supplement : Drustivardhak (proprietary blend).  
Statement of Nutritional Support: Eye Health Support.
10. Name of Supplement : Divyashwas Jivan (proprietary blend).  
Statement of Nutritional Support: Healthy Respiratory Support.
11. Name of Supplement : Garbrakshak (proprietary blend).  
Statement of Nutritional Support: Female Health Support.
12. Name of Supplement : Jivan Rakshak (proprietary blend).  
Statement of Nutritional Support: Circulation Support.

13. Name of Supplement : Jivan Shakti (proprietary blend).  
Statement of Nutritional Support: Supports the Immune System.
14. Name of Supplement : Jwarghna (proprietary blend).  
Statement of Nutritional Support: Supports the Immune System.
15. Name of Supplement : Kaishore Guggul (proprietary blend).  
Statement of Nutritional Support: Joint Health Support.
16. Name of Supplement : Kanthasudhar (proprietary blend).  
Statement of Nutritional Support: For Throat Health.
17. Name of Supplement : Keshia (proprietary blend).  
Statement of Nutritional Support: Healthy Hair Support.
18. Name of Supplement : Keshyog (proprietary blend).  
Statement of Nutritional Support: Healthy Hair Support.
19. Name of Supplement : Kidney Tone (proprietary blend).  
Statement of Nutritional Support: Kidney Health Support.
20. Name of Supplement : Kumarika (proprietary blend).  
Statement of Nutritional Support: Female Health Support.
21. Name of Supplement : Kumariyog (proprietary blend).  
Statement of Nutritional Support: Female Health Support.

22. Name of Supplement : Livtone (proprietary blend).  
Statement of Nutritional Support: Liver Health Support
23. Name of Supplement : Lactovita (proprietary blend).  
Statement of Nutritional Support: Female Health Support.
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24. Name of Supplement : Aampachak (proprietary blend).  
Statement of Nutritional Support: Supports Elimination of Toxins.
25. Name of Supplement : Mind Power (proprietary blend).  
Statement of Nutritional Support: Focus Formula.
26. Name of Supplement : Madhunil (proprietary blend).  
Statement of Nutritional Support: Supports Healthy Blood Sugar Level.
27. Name of Supplement : Mednil (proprietary blend).  
Statement of Nutritional Support: Dieter's Aid Support.
28. Name of Supplement : Madhuyog (proprietary blend).  
Statement of Nutritional Support: Supports Healthy Blood Sugar Level.
29. Name of Supplement : Nidrashanti (proprietary blend).  
Statement of Nutritional Support: Sleep Support for Occasional Sleeplessness.
30. Name of Supplement : Paramsukha (proprietary blend).  
Statement of Nutritional Support: Male System Support.
31. Name of Supplement : Petrog (proprietary blend).  
Statement of Nutritional Support: Abdominal Organ Support.

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97S-0163

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97S-0163



32. Name of Supplement : Prameh (proprietary blend).  
Statement of Nutritional Support: Urinary Health Support.
33. Name of Supplement : Praval Moti (proprietary blend).  
Statement of Nutritional Support: Heat Reducing Formula.
34. Name of Supplement : Putrasanjivani (proprietary blend).  
Statement of Nutritional Support: Female System Support.
35. Name of Supplement : Raktashanti (proprietary blend).  
Statement of Nutritional Support: Circulatory Support.
36. Name of Supplement : Rasanyog (proprietary blend).  
Statement of Nutritional Support: Helps Support the Immune System.
37. Name of Supplement : Rudshakti (proprietary blend).  
Statement of Nutritional Support: Helps Maintain Cardiovascular Health.
38. Name of Supplement : Rumanil (proprietary blend).  
Statement of Nutritional Support: Joint Health Support.
39. Name of Supplement : Sakhi (proprietary blend).  
Statement of Nutritional Support: Female System Support.
40. Name of Supplement : Sandhiyog (proprietary blend).  
Statement of Nutritional Support: Joint Health Support.

41. Name of Supplement : Shakti Rasayana (proprietary blend).  
Statement of Nutritional Support: Rejuvenation Formula.
42. Name of Supplement : Shiva (proprietary blend).  
Statement of Nutritional Support: For Occasional Constipation.
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43. Name of Supplement : Shukravardhak (proprietary blend).  
Statement of Nutritional Support: Male System Support.
44. Name of Supplement : Sitopaladi (proprietary blend).  
Statement of Nutritional Support: For Throat Health.
45. Name of Supplement : Skin Tonic (proprietary blend).  
Statement of Nutritional Support: Supports Healthy Skin
46. Name of Supplement : Special Tonic (proprietary blend).  
Statement of Nutritional Support: Male System Support.
47. Name of Supplement : Subuddhi (proprietary blend).  
Statement of Nutritional Support: Relaxation Formula.
48. Name of Supplement : Virechan (proprietary blend).  
Statement of Nutritional Support: Supports Elimination of Toxins.
49. Name of Supplement : Sudarshan Ghan (proprietary blend).  
Statement of Nutritional Support: Cooling Formula.

50. Name of Supplement : Sukarna (proprietary blend).  
Statement of Nutritional Support: Ear Health Support.
51. Name of Supplement : Suniram (proprietary blend).  
Statement of Nutritional Support: Supports Elimination of Toxins.
52. Name of Supplement : Supachak (proprietary blend).  
Statement of Nutritional Support: Digestive Support.
53. Name of Supplement : Suprabha (proprietary blend).  
Statement of Nutritional Support: Abdominal Organ Support.
54. Name of Supplement : Suhruday (proprietary blend).  
Statement of Nutritional Support: Relaxation Support.
55. Name of Supplement : Suvarna (proprietary blend).  
Statement of Nutritional Support: Healthy Skin Formula.
56. Name of Supplement : Suyog (proprietary blend).  
Statement of Nutritional Support: Digestive Support.
57. Name of Supplement : Twachashuddhi (proprietary blend).  
Statement of Nutritional Support: Skin Support.
58. Name of Supplement : Uritone (proprietary blend).  
Statement of Nutritional Support: Urinary Health Support.
59. Name of Supplement : Vatna (proprietary blend).  
Statement of Nutritional Support: Joint Support.
60. Name of Supplement : Vayushamak (proprietary blend).  
Statement of Nutritional Support: Abdominal Organ Support.

To the best of my knowledge, the information contained in this notice is complete and accurate, and Amrita Veda has substantiation that the statements are truthful and not misleading.

Sincerely,

A handwritten signature in black ink, appearing to read 'Avi Farzan', written over a horizontal line.

Avi Farzan  
President, Amrita Veda