



DEC - 6 2004

Mr. Jim Roza  
Director, Quality Assurance  
NOW Foods  
395 S. Glen Ellyn Road  
Bloomington, Illinois 60108

Dear Mr. Roza:

This is in response to your letters of October 28, 2004 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, among others, will be made for the product Hawthorne Extract: "[H]ealthy 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 pressure; that is, a claim that does not establish that the claims are about blood pressure that is already within normal limits implies that the product is intended to treat elevated blood pressure (hypertension), which is a disease. Therefore, because the claim you are making for this product represents that the product is intended to affect blood pressure but does not also include a statement about it being intended to affect blood pressure that is already in the normal range, it is an implied disease claim.

You also submitted a notification for the product Vein Supreme, which will use the claims "[P]roviding relief from the discomfort of symptoms associated with poor circulation, such as heaviness and swelling of the lower extremities" and "[M]inimize the occurrence of damaged, weakened blood vessels."

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 a disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these product

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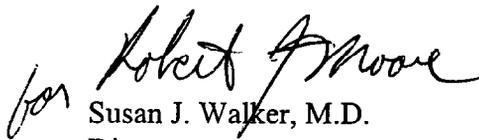
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are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation 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,

for Robert J. Moore

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

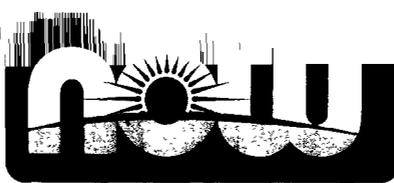
and Applied Nutrition

**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, Chicago District Office, Office of Compliance, HFR-CE640



We Make Quality Affordable

October 28, 2004

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Nutritional Products, Labeling, and Dietary Supplements  
Division of Nutritional Programs and Labeling  
200 C Street SW  
Washington, DC 20204

NOV 30 2004

Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir/Madam:

I hereby notify the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of Vein Supreme, a dietary supplement.

Statements being made in the labeling of Vein Supreme:

(1) Vein Supreme is an herbal supplement containing the patented ingredient, Trunorin, which has been shown to support healthy vein function. In combination with Butcher's Broom (*Ruscus aculeatus*), Horse Chestnut Seed Extract (*Aesculus hippocastanum*), and Grape Seed Extract, NOW's Vein Supreme formula protects vascular integrity, [providing relief from the discomfort of symptoms associated with poor circulation, such as heaviness and swelling of the lower extremities. NOW Vein Supreme is a safe and natural way to enhance vascular tone, as well as to minimize the occurrence of damaged, weakened blood vessels.

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. NOW Foods possesses substantiation that the statements are truthful and not misleading.

Jim Roza  
Director, Quality Assurance  
NOW Foods  
395 S. Glen Ellyn Rd.  
Bloomington, IL 60108



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October 28, 2004

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
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Washington, DC 20204

NOV 30 2004

Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir/Madam:

I hereby notify the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of Hawthorne Extract, a dietary supplement.

Statements being made in the labeling of Hawthorne Extract:

(1) Hawthorne leaves, flowers, and berries have been used for generations by herbalists as a cardiovascular tonic. Hawthorne supports cardiovascular health by enhancing cardiac muscular tone and vascular integrity. NOW Hawthorne Extract provides powerful antioxidant flavonoids, including standardized Vitexin that, along with other components in Hawthorne, have been found to support healthy blood flow and healthy blood pressure.

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. NOW Foods possesses substantiation that the statements are truthful and not misleading.

Jim Roza  
Director, Quality Assurance  
NOW Foods  
395 S. Glen Ellyn Rd.  
Bloomington, IL 60108

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