



FEB -2 2000

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Ms. Edie Moore  
Mr. Sean Hearn  
New Millennium Associates  
SE Life Solutions Division  
P.O. Box 205  
Willow Springs, North Carolina 29592

Dear Ms. Moore and Mr. Hearn:

This is in response to your letter of January 20, 2000 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 New Millennium Associates, SE Life Solutions Division, is making the following claims, among others, for the products:

**Formula One - Anti-Addiction formula**

“...makes you nauseous and/or light Headed if you smoke, makes cigarettes taste bad”

**Formula Two - Denicotizer**

“To remove nicotine from the system, thereby reducing cravings for nicotine”

**Total Serenity - Natural Calming Product**

“...Helps with nervous signs of withdrawal.”

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, mitigate, or prevent disease, namely addiction to nicotine, and are intended for use as smoking cessation aids. 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, 7520 Standish Place, Rockville, Maryland 20855.

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Your submission also states that New Millennium Associates, SE Life Solutions Division is marketing the product "AromaMagic" as a dietary supplement. 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 dietary, and are labeled as a dietary supplement.

This product 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 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, a product that is inhaled to exert its effect is not subject to regulation as a dietary supplement because it is not "intended for ingestion."

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Moreover, the statements that you are making for this product suggests that it may be intended to treat, mitigate, or prevent addiction to nicotine or be intended for use as a smoking cessation aid. Such claims suggest that this product may be intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it may be 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 at the address given above.

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, Atlanta District Office, Office of Compliance, HFR-SE140

cc:

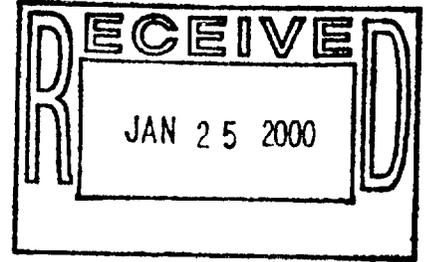
HF-13 (Zeller)  
HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-456 (r.f, file)  
HFS-450 (r/f, file)  
HFD-310 (BWilliams)  
HFD-314 (Aronson)  
HFS-605  
HFV-228 (Betz)  
GCF-1 (Dorsey, Nickerson, Barnett)  
r/d:HFS-456:RMoore:1/31/2000  
reviewed and init:GCF-1:LNickerson:1/31/00  
f/t:HFS-456:rjm:2/1/00:docname:68929.adv:disc44

SE LifeSolutions  
Division of  
NEW MILLENNIUM COMMUNICATIONS  
P.O. BOX 205  
WILLOW SPRINGS, NC 29592  
Phone: 919-552-1832

January 20, 2000

Food and Drug Administration  
Office of Special Nutritional (HFS-450)  
Center for Food Safety and Applied Nutrition  
200 C Street, SW  
Washington, DC 20204

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Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403 ( r ) (6) (21) U.S.C. 343 ( r ) (6) of the Federal Food and drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that SE LifeSolutions a division of New Millennium Associates, P.O. Box 205 Willow Springs, NC 29592, within the past 30 days commenced marketing a dietary supplement bearing the following statement(s) on the label and or labeling.

**Finally Free of Nicotine Addiction** (five part stop smoking system)

Formula One – Anti-Addiction formula. Nutritionally supports the body , makes you nauseous and/or light Headed if you smoke, makes cigarettes taste bad.

Ingredient(s) that is subject to claim above: Vitamin C, Lobelia Powder, Echinacea Powder.

Formula Two – Denicotizer. Helps with natural cleansing, provides nutritional support and assists the body To remove nicotine from the system, thereby reducing cravings for nicotine.

Ingredient(s) that is subject to the claim above: Burdock Root Powder, Barley Grass Powder, Golden Seal Powder, Cascara Sagrada Powder, Dandelion Root.

Total Serenity – Natural Calming Product. Promotes mental clarity and calmness, helps with nervous signs of withdrawal.

Ingredient(s) that is subject to the claim above: St. John's Wort Extract

Body Slim – Helps reduce the urge to eat and promotes fat burning to help keep from gaining weight.

Ingredient(s) that is subject to the claim above: Vitamin C, Vitamin B6, Biotin, Chromium, White Willow Bark.

AromaMagic – Aromatherapy system used to combat cravings or urges to smoke or eat.

Ingredients(s) that is subject to the claim above: Ylang Ylang Oil, Rosemary Oil, Peppermint Oil, Camphor Oil, Eucalyptus Oil.

The undersigned certifies that the information contained in this notice is complete and accurate and that SE LifeSolutions a division of New Millennium Associates has substantiation that the statement is truthful and not misleading.

Sincerely,

*Eddie Moore Sean Hearn*

Eddie Moore & Sean Hearn  
New Millennium Associates