DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

8528 '01 AUG -8 P2:21

JUL 31 2001

President
Neways, Inc.
150 East 400 North
Salem, Utah 84653

Dear Sir:

This is in response to your letter of July 5, 2001 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 Neways, Inc. is making the following claim for the product **Silence**:

> "For those who snore."

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.

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

975-0163

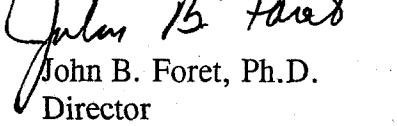
LET 530

> 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 intended to be "spray[ed] 6 times into mouth toward back of throat prior to sleep or desired activity. Do not eat or drink after application" is not subject to regulation as a dietary supplement because it is not "intended for ingestion" because it is applied in the mouth/throat where it is intended to act prior to being ingested.

Please contact us if we may be of further assistance.

Sincerely,



John B. Foret, Ph.D.
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, Denver District Office, Office of Compliance, HFR-SW240

NOTICE OF STATEMENT

Pursuant to 21 CFR 101.93

To: Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW.
Washington, D.C. 20204

RECEIVED
JUL - 9 2001

a. Name and address of manufacturer or distributor:

76704

Neways, Inc.
150 East 400 North
Salem, UT 84653

b. The text of the statement:

For those who snore

c. The name of the dietary ingredient or supplement:

Methylsulfonylmethane (MSM), grape seed, safflower, evening primrose, and apricot kernel cold pressed oils, elecampane extract and cinnamon bark, clove bud, eucalyptus and lavender essential oils.

c. The name of the dietary supplement including brand name:

Silence

Responsible Person

Signature	Title	Date
	President	7/5/01

SILENCE™

for
those
who
snore

Dietary Supplement

30 ml / 1 oz

Supplement Facts

Serving Size 0.72 ml
Servings Per Container 42

Amount Per Serving		% Daily Value
Calories	5	
Total Fats	0.5 g	< 1%*
Vitamin E (as d-alpha tocopheryl acetate)	40 IU	132%
Methylsulfonylmethane (MSM)	3 mg †	
Proprietary Blend	0.63 g †	

Grape seed, safflower, evening primrose, and apricot kernel cold pressed oils, elecampane extract, and cinnamon bark, clove bud, eucalyptus, and lavender essential oils.

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: water, propanetriol, glycerylmonostearate, polysorbate 20 and sucralose.
DIRECTIONS: Shake before use. Spray 6 times into mouth toward back of throat prior to sleep or desired activity. Do not eat or drink after application.
CAUTION: See your health care provider prior to use if you are pregnant or nursing, have a medical condition, or when taking any medication.

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

LBL 0393/1 • ITEM #2848
Neways Aromatherapy
Salem, Utah 84653
Made in the U.S.A.