



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

1353 04 07-4 1257

OCT 28 2004

James Meschino, DC, MS
President
Adëeva Nutritionals Canada, Inc.
3800 Steeles Avenue West
Suite 401 W
Woodbridge, Ontario L4L 4G9
Canada

Dear Dr. Meschino:

This is in response to your letter to the Food and Drug Administration (FDA), dated September 23, 2004, 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 Adëeva Nutritionals Canada, Inc. is marketing the product Adëeva Orega-Skin cream for external or topical uses. The product is described as "Apply topically as a moisturizing, rejuvenating cream" and is, among things, promoted as "ideal for various skin disorders."

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 diet, and are labeled as a dietary supplement.

An article that is applied externally to the skin 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:

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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, products that are intended to be used topically are not subject to regulation as dietary supplements because they are not "intended for ingestion" and may be drugs under 21 U.S.C. 321(g)(1)(C) because they are articles (other than food) intended to affect the structure or function of the body.

Please contact us if we may be of further assistance.

Sincerely yours,



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

Adëeva

September 23, 2004

SEP 28 2004

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling and Dietary Supplements
US Food & Drug Administration
5100 Paint Branch Parkway
College Park, MD
20740

Via Courier

Dear Sirs:

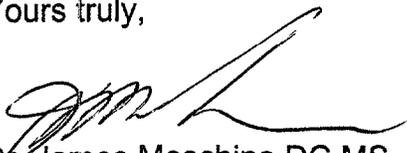
Please find attached a copy of the labels and boxes for two new items being added to our Adëeva line of products we are going to begin distributing in the near future.

These labels contain statements allowed for under section 403 (r) (6) of the Federal Food, Drug & Cosmetic Act.

As President of this company, I hereby certify that the statements made are complete and accurate and our company has substantiation that the statements are truthful and not misleading.

Should you require any further information with regards to this matter, please contact me at 1-877-264-8080.

Yours truly,



Dr. James Meschino DC,MS.
President, Adëeva Nutritionals Canada Inc.

89907

Actual Seize
Label

DIRECTIONS: Apply topically as a moisturizing, rejuvenating cream. Repeat as necessary. Avoid contact with eyes.

MODE D'EMPLOI: Application topique comme crème hydratante, rajeunissante. Appliquer à nouveau, selon les besoins. Éviter tout contact avec les yeux.

Distributed by/Distribué par:
Adëeva Nutritionals Canada Inc.
3800 Steeles Ave. West, Suite 201W
Woodbridge, ON L4L 4G9
1-877-264-8080
www.adëeva.com

Adëeva™
ESSENTIAL BEAUTY
PROGRAM

PROGRAMME DE
BEAUTÉ ESSENTIEL

Orega-Skin

100% Naturally Sourced
À base de produits entièrement naturels
Researched • Tested • P73
Soumis à des recherches et à des essais
2 oz (60 ml) Cream / Crème



Orega-Skin cream is a powerful rejuvenating formula containing propolis, essential oils, and wild honey. Great for all skin types. It's ideal for various skin disorders and maintaining skin health.

La crème Orega-Skin est une formule rajeunissante très active qui contient de la propolis, des huiles essentielles et du miel sauvage. Convient à tous les types de peaux. Idéale pour éliminer divers troubles cutanés et garder la peau en bonne santé.

Ingredients: Purified water, Canadian wildflower honey, propolis, royal jelly, St. John's wort oil, wild oil of oregano P73, wild lavender oil, wild myrtle oil, extra virgin olive oil, and pure essence of Canadian balsam.

Ingédients: Eau pure, miel de fleurs sauvages du Canada, propolis, gelée royale, essence de millepertuis, essence d'origan sauvage P73, essence de lavande sauvage, essence de myrte sauvage, huile d'olive extra vierge et essence de baume du Canada pur.

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