



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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DEC 14 2005

Mr. Andrew Garcia
Miracle Breakthrough Labs, Inc.
7296 Southwest 48th Street
Miami, Florida 33155

Dear Mr. Garcia:

This is in response to your letters to the Food and Drug Administration (FDA), dated November 30, 2005, 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 Miracle Breakthrough Labs, Inc. is marketing the products two products as dietary supplements that appear to be for external use; namely, **Erection Instant Wipes** and **Erection Maximizer Cream**.

These products do 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 dietary supplements. 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:

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.")...

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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 are 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,



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, Florida District Office, Compliance Branch, HFR-SE240

Miracle Breakthrough Lab, Inc.

Office of Nutritional Products,
Labeling, and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition,
Food And Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

DEC 1 2005

NOTIFICATION PURSUANT TO SECTION 6 OF DSHEA AND 21 CFR §101.93.

This notification is being filed on behalf of Miracle Breakthrough Labs, Inc., which is the manufacturer of the product which bears the statements identified in this notification. Its business address is:

Executive Office:
Miracle Breakthrough Lab, Inc.
7296 S.W. 48th St.
Miami, FL 33155

This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label and labeling the statements appear is Erection Maximizer Cream.

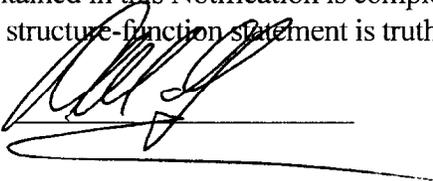
The text of each statement for which notification is now being given is as follows:

Statement 1: This product uses ingredients that may be helpful in maximizing your erection size and duration.

The following identifies the brand name of the supplement for which a statement is made.

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label/Labeling</u>
1	Miracle Breakthrough Labs	labeling

I, Andrew Garcia, am authorized to certify this Notification on behalf of Miracle Breakthrough Labs, Inc. I certify that the information presented and contained in this Notification is complete and accurate, that Miracle Breakthrough Labs, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 11/30, 2005 By: 

Executive Offices
7296 Southwest 48th Street, Miami, Florida 33155 • PO Box 145087, Coral Gables, Florida 33114-5087
305.284.8858 • 305.663.9912 Facsimile

05-8226

Miracle Breakthrough Lab, Inc.

November 30, 2005

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Office of Nutritional Products,
Labeling, and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition,
Food And Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

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Executive Office:
Miracle Breakthrough Lab, Inc.
7296 S.W. 48th St.
Miami, FL 33155

This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label and labeling the statements appear is Erection Instant Wipes.

The text of each statement for which notification is now being given is as follows:

Statement 1: This product uses ingredients that may be helpful in maximizing your erection size and duration.

The following identifies the brand name of the supplement for which a statement is made.

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label/Labeling</u>
1	Miracle Breakthrough Labs	labeling

I, Andrew Garcia, am authorized to certify this Notification on behalf of Miracle Breakthrough Labs, Inc. I certify that the information presented and contained in this Notification is complete and accurate, that Miracle Breakthrough Labs, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 11/30/2005, 2005 By: [Signature]

2005-8224

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