



MAY - 5 2004

Mr. Michael Pelton
Vice President
Biotech Corporation, Inc.
107 Oakwood Drive
Glastonbury, Connecticut 06033

Dear Mr. Pelton:

This is in response to your letters to the Food and Drug Administration (FDA), dated February 20, 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 Biotech Corporation, Inc. intends to market **Shen Min® Triple Action Starter Kit** and **Nu Hair™ Triple Action Starter Kit** using the following claims:

- "...Advanced Hair Regrowth tablets..."
- "...Concentrated Action Topical Solution..."
- "...a nutraceutical anti-thinning tablet that provides intensive nourishment..."
- "...natural nutrient booster...to nourish the hair..."
- "...100% natural tablet formula..."

At least one product in these kits does not 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.

An article that is delivered orally, but that exerts its effect prior to being swallowed (for example, as a mouthwash that will act directly on the gums, 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

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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 used externally (i.e., a topical solution) is not subject to regulation as a dietary supplement because it is not "intended for ingestion" and appears to be a drug under 21 U.S.C. 321(g)(1)(C) because it is an article (other than food) intended to affect the structure or function of the body.

If you have questions about the marketing of this product as a drug, 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 20852.

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

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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, New England District Office, Compliance Branch, NWE-NE340

BIOTECH CORPORATION

February 20, 2004

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

MAR 25 2004

Re: Notification of DSHEA nutritional support claims for BioTech Corporation, Inc
Shen Min® Triple Action Starter Kit Dietary Supplement

The purpose of this letter is to provide notification pursuant to section 403 (r)(6) of the Federal Food, Drug and Cosmetic Act ("the Act") and 7 C.F.R. & 101.93 that BioTech Corporation, Inc. is marketing a dietary supplement that bears a statement of nutritional support as defined in section 403 (r)(6) of the Act.

The labeling for the Shen Min® Triple Action Starter Kit bears the following statements:

1. "...Advanced Hair Regrowth tablets..."
2. "...Concentrated Action Topical Solution..."
3. "...a nutraceutical anti-thinning tablet that provides intensive nourishment..."
4. "...natural nutrient booster...to nourish the hair..."
5. "...100% natural tablet formula..."

BioTech Corporation, Inc has on file substantiation that the above statements are truthful and not misleading. To the best of my knowledge, the information contained in this notice is complete and accurate.

Sincerely,

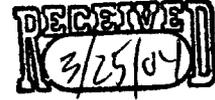


Michael Pelton
Vice President

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February 20, 2004

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

Re: Notification of DSHEA nutritional support claims for BioTech Corporation, Inc Nu Hair™ Triple Action Starter Kit Dietary Supplement

The purpose of this letter is to provide notification pursuant to section 403 (r)(6) of the Federal Food, Drug and Cosmetic Act ("the Act") and 7 C.F.R. & 101.93 that BioTech Corporation, Inc. is marketing a dietary supplement that bears a statement of nutritional support as defined in section 403 (r)(6) of the Act.

The labeling for the Nu Hair™ Triple Action Starter Kit bears the following statements:

1. "...Advanced Hair Regrowth tablets..."
2. "...Concentrated Action Topical Solution..."
3. "...a nutraceutical anti-thinning tablet that provides intensive nourishment..."
4. "...natural nutrient booster...to nourish the hair..."
5. "...100% natural tablet formula..."

BioTech Corporation, Inc has on file substantiation that the above statements are truthful and not misleading. To the best of my knowledge, the information contained in this notice is complete and accurate.

Sincerely,

Michael Pelton
Vice President

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