



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

95195d

Food and Drug Administration
Denver District Office
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Denver, Colorado 80225-0087
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January 20, 2005

AMENDED WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Dennis Gay
Chief Executive Officer
Basic Research, LLC
5742 W. Harold Gatty Drive
Salt Lake City, Utah 84116

Ref#: Den 05-06 Amended

Dear Mr. Gay:

We are amending our Warning Letter of January 14, 2005 to include your products MamrÄlin-ARa, and TestroGel and are re-issuing the letter with a January 20, 2005 date. Your expected date of response for all five products is now extended to fifteen working days after this later date.

This letter is in reference to your firm's marketing and distribution of StriVectin-SD, StriVectin-SD Eye Cream, Dermalin-APg, MamrÄlin-ARa, and TestroGel. The Food and Drug Administration (FDA) has reviewed the labeling for these products, including your websites at www.kleinbecker.com and www.strivectin.com. FDA has determined that your products StriVectin-SD, StriVectin-SD Eye Cream, Dermalin-APg, MamrÄlin-ARa, and TestroGel are promoted with claims that cause the products to be drugs under section 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 321(g)(1)(C)).

As defined in section 201(g)(1)(C) of the Act, the term "drug" means articles (other than food) intended to affect the structure or function of the body. The labeling for your products includes several claims that demonstrate that these products are intended to affect the structure or function the body (structure/function claims). Examples of some of the structure/function claims observed in your products' labeling include:

StriVectin-SD:

- "Intensive Concentrate For Existing Stretch Marks (Striae Distensae)"
- "Clinically Proven to Dramatically Reduce the Appearance of Existing Stretch Mark Length, Depth, Texture, and Discoloration"

- “Optimum Glycosaminoglycan and Collagen Synthesis”
- “Better than Botox®?”
- “A stretch-mark reducing emulsion ... to diminish fine lines, wrinkles and crow’s feet.”
- “[S]uperior wrinkle-reducing properties of a patented oligo-peptide (called Pal-KTTKS) ... on ‘photo-aged skin’.... [A] key ingredient in the StriVectin cream.”
“[S]ignificant improvement’ in wrinkle depth, length, wrinkle volume”
- “Pal-KTTKS solution’s effectiveness at reducing the appearance of fine lines and wrinkles...”
- “StriVectin-SD actually increases the synthesis of new collagen (StriVectin-SD increases collagen I synthesis by 117%, increases collagen IV synthesis by 357%, and increases glycosaminoglycan synthesis by 267%), making your skin thicker and firmer.”
- “StriVectin-SD’s clinically proven, proprietary compounds will produce a visible reduction in actual length, size, depth, feel, color, and rough texture of your existing wrinkles and/or stretch marks.”
- “[R]educe wrinkles by as much as 68%, ... and reduce the actual length, depth, volume, and surface area of stretch marks/wrinkles.”
- “Q: Can StriVectin-SD® help with acne scars and other types of scarring?
A: Yes.... StriVectin-SD users have reported improvement in acne scars, burn scars, chicken pox marks, scars from old injuries, etc.”
- “93% of the subjects tested saw a dramatic difference in the depth, length, feel, color, and texture of stretch marks.”
- “Repair Existing Stretch Marks”
- “[C]linical observations further document the independent active StriVectin-SD isolates dramatically:
 - Decreased the actual length of striae (stretch marks)
 - Decreased the depth of indented surfaces
 - Increased smooth surfaces
 - Increased skin thickness
 - Increased skin firmness
 - Increased stimulation of collagen synthesis
 - Corrected irregularities in skin coloration”“StriVectin-SD: The Most Effective Stretch Mark Repair Compound Ever Developed”
- “[P]roven ability to significantly eradicate the scarred striations of stretch marks....”

StriVectin-SD Eye Cream (www.strivectin.com):

- “Same active formula as the original StriVectin-SD®”
- “StriVectin-SD (the stretch-mark-reducer-turned-anti-wrinkle-phenomenon
- “[S]ignificant decrease in your existing wrinkles or stretch marks”

Dermalin-APg (www.kleinbecker.com):

- “The next-generation transepidermal fat emulsifying gel”

- “Penetrating Gel Emulsifies Fat On Contact”
- “Dissolves Deep-Stored Body Fat Wherever Applied.”
“[R]educes the accumulation of ‘age-related’ body fat around your waist and abdomen.”
- “[A]ctually reduce the size of ‘saddlebag’ thighs.”
- “[P]enetrates the skin and shrink a woman’s thigh.”
- “[R]eleases fat stores from any problem area. When the fat is released from the back of a woman’s thigh, the dimpled appearance disappears because tension on the connective tissue is reduced as stored ‘depot’ fat is released. However, when the gel is applied to the tummy, waist or hips, a dramatic reduction of stored body fat occurs”
“Just apply...to your waist or tummy and watch them shrink in size within a matter of days.”
- “Wherever you’ve got those unsightly lumps and bumps, apply Dermalin-APg and they’re gone.”
- “[F]orces the fat out of adipose tissue cells”
- “[O]ne problem area at a time, until you’ve literally melted the fat and molded your body into a more pleasing shape.”

MamrÄlin-ARa (www.kleinbecker.com)

- “[D]esigned to protect a woman’s breasts from sag and shrinkage caused by weight loss.”
- “The Adenosine Receptor Agonists (ARAs) in MamrÄlin-ARa are designed to protect (and in many cases increase) the figure-enhancing fat stores in your bust”
- “[I]nhibiting lipolysis (the process that causes the breast to release stored fat) and stimulating fat uptake and retention.”
- “[M]akes it difficult for your body to deplete the fat stores in you breast for energy ... maintaining (and in many cases increasing) the figure-enhancing fat stores in your bust”
- “[H]elping you get rid of the excess, unwanted fat stored in your hips, thighs, abs, and buttocks”
- “[A]pplying MamrÄlin-ARa twice a day is the best way to avoid diet induced breast sag and shrinkage.”

TestroGel (www.kleinbecker.com)

- “TestroGel for Sexual Enhancement”
- “[Q]uickly raising androgen levels to give you (and your partner) the sexual confidence, stamina, and intensity it takes to truly satisfy...and be satisfied.”
- “Testosterone-Boosting Gel ...”
- “[R]aise your testosterone levels without a doctor’s prescription”
- “Increase Testosterone Without Raising Estradiol Levels”
- “[S]uddenly become bigger, more ripped, more powerful, and more aggressive”
- “[H]ave more muscle mass, more strength, and less body fat”
- “[A] clinically verified alternative to prescription performance enhancers.”

Furthermore, your products are not generally recognized as safe and effective for the above referenced uses and therefore, the products are considered “new drugs” under section 201(p) of the Act. New drugs may not be legally marketed in the U.S. without prior approval from FDA [section 505(a) of the Act].

This letter is not intended to be an all inclusive review of all claims, labeling, or products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action without further notice. The Act provides for the seizure of illegal products, injunctions against the manufacturer and/or distributor of illegal products, and criminal sanctions against persons responsible for causing violations of the Act.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify violations and make corrections to ensure that similar violations will not recur. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be implemented.

Any reply should be sent to the attention of Compliance Officer Shelly L. Maifarth at the above address.

Sincerely,



B. Belinda Collins
District Director