



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 758-7132
FAX: (612) 334-4142

February 15, 2007

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 07 - 12

Steve Basta
President and Chief Executive Officer
BioForm Medical, Inc.
1875 South Grant Street, Suite #110
San Mateo, California 94402

Dear Mr. Basta:

The Food and Drug Administration (FDA) conducted an inspection of your facility at 4133 Courtney Road, Suite 10, Franksville, WI, from October 2-18, 2006. During that inspection, the investigator collected labels and product inserts for your Cutanix Dramatic Relief for Oily and Acne Prone Skin, Cutanix Dramatic Relief for Normal to Dry Skin, Cutanix Dramatic Relief for Sensitive Skin, and Cutanix Dramatic Relief Extra Strength products. In addition, the FDA reviewed your web sites at www.bioformmedical.com, www.tvdepot.com/getridofthered/ and www.cutanix.com.

The review of this labeling found the products being offered are promoted for conditions that cause them to be drugs under sections 201(g)(1)(B) and 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(g)(1)(B) and 321(g)(1)(C)]. Claims in your labeling, including your web sites, establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease and are intended to affect the structure or function of the body. You can find the Act and FDA's regulations through links on FDA's Internet home page, <http://www.fda.gov>.

Examples of some of the claims observed for these products include:

Claims on the boxes for each of your Cutanix products:

- "Reduces Redness"
- "Smoothes Scaly Skin"

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Claims on the Cutanix Dramatic Relief for Oily and Acne Prone Skin box:

- “[I]ntended for individuals with chronic skin redness and flaking...associated with dermatologic conditions like seborrheic dermatitis or rosacea.” (Claim also observed on your product insert and on your web site www.tvdepot.com.)
- “Inflamed oily skin associated with troublesome dermatologic conditions...Dramatic Relief...for Oily and Acne Prone Skin...clinically proven to reduce redness, eliminate scaling, and help soft, smooth skin reappear.”

Claims on the Cutanix Dramatic Relief for Normal To Dry Skin box:

- “[I]ntended for individuals with chronic skin redness accompanied by severely dry skin, often associated with dermatologic inflammatory conditions like eczema or rosacea.” (Claim also observed on your product insert and on your web site www.tvdepot.com.)
- “Inflamed, dry and scaly skin often associated with troublesome dermatologic conditions... Dramatic Relief...for Normal to Dry Skin ...clinically proven to reduce redness, eliminate scaling and itching, and help smooth, soft skin reappear.”

Claims on the Cutanix Dramatic Relief for Sensitive Skin box:

- “[I]ntended for individuals with chronic facial redness...often associated with dermatologic conditions like rosacea or eczema.” (Claim also observed on your product insert and your web site www.tvdepot.com.)
- “[S]ymptoms associated with troublesome dermatologic conditions like rosacea, eczema or seborrheic dermatitis.... Dramatic Relief...for Sensitive Skin...clinically proven to reduce redness, eliminate itching and scaling; and help smooth, soft skin reappear.”

Claims on the Cutanix Dramatic Relief Extra Strength box:

- “[I]ntended for individuals with chronic, persistent facial redness associated with dermatologic inflammatory conditions like rosacea or eczema.” (Claim also observed on your product insert.)
- “[F]or individuals with troublesome dermatologic conditions requiring intensive therapeutic treatment like rosacea, eczema, or seborrheic dermatitis.”
- “[C]linically proven therapeutic formulation will reduce stubborn, persistent redness, eliminate itching and scaling, and help soft, smooth skin reappear.”

Additional claims on the package insert that accompanies each of your Cutanix products:

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- “[S]oothing, healing effect on dry, inflamed skin.”
- (Under the heading “Cutanix Dramatic Relief Clinical trials”)
“[E]ffectiveness of Dramatic Relief in improving the following symptoms often associated with rosacea or eczema-prone skin...
Reduce Redness √
Soothes Scaly Skin √
Evens Skin Tone √
Relieves Itching, Stinging and Burning √”
- (Under the heading “Cutanix Dramatic Relief Clinical trials”)
“71% of participants demonstrated reduction in redness
88% of those with scaly skin had marked reduction of scaling...
69% of participants demonstrated an improvement in skin tone
92% of those reporting itching, stinging or burning prior to the study reported a reduction in one or more symptoms....”
- “Clinical trial results demonstrated the effectiveness of Dramatic Relief in alleviating scaly skin and uneven skin tone....”

Additional claims observed on your web sites www.tvdepot.com and www.cutanix.com (which automatically sends visitors to your www.tvdepot.com web site):

- “Millions of men and women suffer the stinging embarrassment of chronic facial redness and flushing.... Now there’s Cutanix.”
- “Overnight I could feel the roughness of the eczema go away.”
- “Cutanix Dramatic Relief is a safe and gentle topical product that’s proven to calm and soothe red, dry skin, without a prescription.”
- “You don’t have to put up with red, dry, flaky, itchy, irritated skin and you don’t need to use a prescription medication....”
- “After I tried Cutanix, my face wasn’t lighting on fire anymore.”
- “[Cutanix] Dramatic Relief is clinically proven to:
Relieve itching, stinging and burning of the skin
Reduce Redness of the skin
Improve skin tone”
- “The body releases inflammatory triggers and immune cells that cause the skin to become red, swollen, itchy and painful.... Cutanix is specially formulated to pass through the skin’s outer surface to calm the inflammatory process and help get rid of the red.”
- (Under the heading “Dramatic Relief Clinical Trial Results”)
“75% of participants demonstrated either elimination or reduction in skin redness
88% of those with scaly skin had no evidence of scaling by the end of the study
69% of participants demonstrated an improvement in skin tone
92% of those reporting itching, stinging or burning prior to the study reported a reduction in one or more skin symptoms....”

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- "Dramatic Relief is effective in relieving the redness, roughness, scaling and dryness commonly associated with rosacea, seborrheic dermatitis, eczema, or allergic dermatitis (ex., poison ivy, poison oak), sunburn, and insect bites."
- "Individuals using Dramatic Relief for conditions such as sunburn, mosquito bites, and poison ivy have noticed significant improvement...and relief from itching immediately."
- "I was always flushed. I was always red.... I tried Cutanix and my skin cleared up enormously."
- "Before I tried Cutanix [I had] dry, patchy skin that would flare up and break out.... It cooled my face and got down the red tones."
- "I was suffering from eczema, my skin around my eyes was really flaky.... I tried Cutanix.... [O]vernight I could feel the roughness go away.... I've had no breakouts from eczema at all."
- "Before I tried Cutanix...my face would...light on fire and burn, and...get bright red.... Within a week of trying Cutanix I noticed...considerable improvement in my skin. My skin wasn't lighting on fire anymore. Looking in the mirror now, seeing my natural rosy skin, rather than the hot, red skin...."
- "I have funny red spots, particularly around my cheek, my forehead area and my chin.... Cutanix has been a wonderful experience. My skin tone has evened out. I feel like the specific problem areas have gotten considerably better."
- "[A]s I've matured, I've had itchy, scaly skin, redness around my hairline, my nose and around my forehead and eyebrows.... Since I've been using Cutanix the improvement in my skin has been life-changing. I have no dryness, at my nose and in-between my brows. I don't see any flakes falling!"
- "My skin prior to using Cutanix was really red and sensitive...and irritated feeling.... Cutanix made a big difference on my skin."
- "Before Cutanix...[I] saw tons of discoloration, blotches and bumps. There was red in my cheeks; the embarrassing kind of red where you look flushed or stressed or blushing.... After using Cutanix for 8 weeks, I definitely had HUGE results, my skin is more even toned, and I don't...see a million different colors or bumps."

These claims on your product labeling cause your products to be drugs, as defined in sections 201(g)(1)(B) and 201(g)(1)(C) of the Act [21 U.S.C. 321(g)(1)(B) and 321(g)(1)(C)]. Because these drugs are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in section 201(p) of the Act [21 U.S.C. 321(p)]. Under section 505(a) of the Act [21 U.S.C. 355(a)], a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA). FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

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This letter is not intended to be an all-inclusive review of deficiencies in your products and their labeling, including any brochures that accompany the products. You are responsible for ensuring that products marketed by your firm are in compliance with the Act and its implementing regulations.

We may take further action without notice if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please notify this office in writing within 15 working days of receipt of this letter of the specific actions you are taking to correct these violations and to prevent the recurrence of similar violations. You should include in your response documentation such as revised labels, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining violations.

Your written response should be sent to Brian D. Garthwaite, Ph.D., Compliance Officer, at the address located on the letterhead. If you have any questions about this letter, please contact Dr. Garthwaite at (612) 758-7132.

Sincerely,

H. Tomlinson for:
W. Charles Becoat
Director
Minneapolis District

BDG/ccl
DE

xc: Dean Erickson
Vice President and General Manager, Wisconsin Operations
BioForm Medical, Inc.
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Franksville, Wisconsin 53126-9127