



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service  
Food and Drug Administration  
Los Angeles District

19701 Fairchild  
Irvine, California 92612-2506  
Telephone (949) 608-2900

**WARNING LETTER**

**VIA FEDERAL EXPRESS**

January 22, 2004

W/L: 21-04

Raymond J. Francis  
President & CEO  
University Medical Products USA, Inc.  
16912 Von Karman Avenue  
Irvine, CA 92606

Dear Mr. Francis:

This letter is in reference to your firm's marketing and distribution of FACE LIFT Collagen 5 products, including Cell Regeneration Cream, Intensive Wrinkle Reducing Cream, and Intensive Lifting Complex; FACE LIFT Daytime Advanced Retinol-A, Nighttime Advanced Retinol-A, Advanced Under Eye Therapy, Vitamin C Anti-Wrinkle Patch, and Overnight Moisturizer; and BODY LIFT Anti-Cellulite Thigh Cream, Weight Reducing Cream, and Anti-Water Retention Lotion. Labeling for these products includes claims that establish their intended use to affect the structure or function of the body, which causes the products to be drugs, as defined in Section 201(g)(1)(C) of the Federal Food, Drug and Cosmetic Act (the Act).

Objectionable claims that appear on the package labels for the three FACE LIFT Collagen 5 products listed above include the following:

- **Collagen5™ is proven to reduce deep wrinkles up to...70%.**
- Stimulates your skin's own collagen building network.
- Reduces deep wrinkles from within the skin's surface....
- Visible results that won't fade away....

Objectionable claims by product include:

Cell Regeneration Cream

- Helps boost collagen production
- Reduces deep wrinkles up to 70%
- Visibly Reduces Deep Wrinkles plus Fine Lines

Intensive Wrinkle Reducing Cream

- Helps boost collagen levels...
- Reduces deep wrinkles up to 70%

Intensive Lifting Complex

- Enhances collagen production

In addition, the product names “Cell Regeneration Cream” and “Intensive Wrinkle Reducing Cream” imply an effect on the structure or function of the body.

Objectionable claims that appear on the package labels for the BODY LIFT products include the following:

Anti-Cellulite Thigh Cream

- Significantly Reduces...Thigh Circumference
- Stimulate the beta receptors in cells to release stored fat.
- Clinically proven to...reduce thigh circumference.”

Weight Reducing Cream

- **Fat Burning Formula**
- Controls appetite and Increases Metabolism
- Lose Inches & Pounds
- Helps control your appetite and break down unwanted fat....
- Help shed unwanted fat....
- Stimulates your body’s natural ability to break down fat cells, helping to suppress the appetite, accelerate metabolism and burn fat.

Anti-Water Retention Lotion

- Eliminates Bloating & Water Retention
- Helps reduce water retention in the stomach, hips and legs....

In addition, the product names “Weight Reducing Cream” and “Anti-Water Retention Lotion” imply an effect on the structure or function of the body.

Your Internet web site, [www.universitymedical.com](http://www.universitymedical.com), also includes claims about the FACE LIFT Collagen 5 products and other products you market that similarly establish the intended use of these products as drugs. Objectionable claims on your website include the following:

FACE LIFT Collagen 5 Products (listed on website as "Collagen 5 for Deep Wrinkles")

- The only advanced collagen replenishment line....
- Replenishes your skin’s own, natural collagen.
- Reduced deep wrinkles up to 70% in clinical studies.

Daytime Advanced Retinol-A™ and Nighttime Advanced Retinol-A™

- Help stimulate collagen and elastin renewal.

Advanced Under Eye Therapy™

- Effective active ingredients Vitamin C and Retinol-A help visibly firm and smooth away fine lines and wrinkles.
- Green Tea extract helps reduce puffiness, while...healing ingredients help to fade dark circles”

Vitamin C Anti-Wrinkle Patch™

- Vitamin C helps reduce the effects of aging...by helping to strengthen collagen and elastin fibers.
- Clinical studies proved a 50% reduction in wrinkles....

Overnight Moisturizer™

- Helps to calm, relax and promote restful sleep.
- Helps skin cells renew and repair themselves....

Because these drugs are not generally recognized as safe and effective when used as labeled, they are new drugs under section 201(p) of the Act. A new drug may not be legally marketed in this country without an approved New Drug Application (NDA) [Section 505(a) of the Act].

This letter is not intended to be an all inclusive review of the labeling for all products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance 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 being initiated by the Food and Drug Administration without further notice. The Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

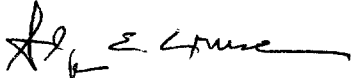
Please notify this office in writing within fifteen (15) working days of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to assure that similar violations will not recur. If the corrective action cannot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

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Your reply should be sent to the Food and Drug Administration, Los Angeles District Office, 19701 Fairchild Street, Irvine, CA 92612. If you have any questions relating to this letter, please contact Barbara Rincon, Compliance Officer at (949) 608-4439.

Sincerely,

A handwritten signature in black ink, appearing to read "Aloha E. Cruse". The signature is stylized with a large initial "A" and a long horizontal stroke at the end.

Aloha E. Cruse

Director, Los Angeles District