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SEP 26 2005

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Randy Moss
President
Hydroderm Beverly Hills

8500 Higuera St.
Culver City, CA 90232

226 S. Beverly Drive
Beverly Hills, CA 90212

11240 Playa Ct.
Culver City, CA 90230

Dear Mr. Moss:

This letter is in reference to your firm's marketing and distribution of your Hydroderm brand products Body Shape Cellulite Toning Lotion, Fast-Acting Wrinkle Remover, Anti-Aging Eye Complex, and Intense Oil-Free Facial Moisturizer. The Food and Drug Administration (FDA) has reviewed your Internet web site at www.hydroderm.com (also accessible through www.hderm.com) and additional labeling for Body Shape Cellulite Toning Lotion, including the literature that accompanies this product when shipped to customers. This review shows serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of the above-listed products. You can find the Act and implementing regulations through links on FDA's Internet website at www.fda.gov.

Under the Act, articles (other than food) intended to affect the structure or any function of the body of man are drugs [Section 201(g)(1)(C) of the Act, 21 USC 321(g)(1)(C)]. The labeling for your products includes claims that demonstrate that these products are intended to affect the structure or function of the body (structure/function claims). Examples of some of the structure/function claims observed in your products' labeling include:

Body Shape Cellulite Toning Lotion

- The product name implies structure/function effect. The combination of the terms “body shape” and “cellulite toning” imply that the product will affect the shape of the body by toning or reducing a type of subcutaneous fat (cellulite).
- Booklet entitled “body shape: cellulite reduction cream”
 - title of booklet
 - “This revolutionary cellulite reduction and slimming lotion will give you dramatic results”
 - “[T]he final step to your weight loss plan.”
 - “Body Shape is clinically proven to...decreas[e] the fat layer on certain parts of the body. Body Shape’s formula works by dehydrating the fat cells, reducing that ‘cottage cheese’ appearance....”
 - “Body Shape is Clinically Proven to: ...
 - Reduce cellulite and diminish stretch marks
 - Increase metabolism in your body’s fat cells”
 - “Body Shape uses a patented liposome delivery system, which transports the ingredients directly through the skin and into the fat cells. The active ingredients then dehydrate the fat cells, reducing the size of the individual fat cells and the thickness of the fat layer.”
 - “Subjects were tested for 60 days and they lost up to 14% of the fat layer in the stomach area and up to 2.1 inches per thigh!”
 - “Body Shape blocks an enzyme called phosphodiesterase, which is responsible for slowing down the fat breakdown process. When phosphodiesterase is being blocked, the fat breakdown process is sped up.”
 - “Men and women have been looking for ways to reduce inches in their stomach, thighs, arms and hip area and Body Shape has helped people reach their objectives.”
 - “This product can also been [sic] used on stretch marks and cellulite.”
 - “[S]ometimes it is virtually impossible to reduce fat in certain parts of your body. That is where Body Shape comes in.”
- Pamphlet entitled “Body Shape: cellulite reduction cream”
 - “Whether you’re trying to get rid of the stretch marks from a childhood growth spurt or are looking to slim down for summer, Body Shape can help you achieve your goals.”
 - “Body Shape is the ‘secret weapon’ that will help tone and firm the areas that exercise alone can’t shape.”
- Additional claims that appear on your Internet web site www.hydroderm.com (claims already cited above are not included):
 - “Body Shape is perfect for men and women who are looking to reduce cellulite while firming and toning their body.”

- “Simply by massaging Body Shape into your skin twice a day, you can tone and firm those problem areas that diet and exercise can’t shape on their own.”
- “Body Shape employs a liposome delivery system to transport its active ingredients.... These natural compounds help dehydrate fat cells, reducing their size and smoothing cellulite.”
- “Its scientific delivery system actually helps target cellulite and unsightly fat deposits on the body.”
- “Body Shape helps your body by:
 - Reducing Cellulite...
 - Dehydrating & Shrinking Fat Cells”

Your website also includes claims in the form of testimonials. Some examples are as follows:

- “I am a certified personal trainer and have worked out for at least 15 years and have a very low fat diet but it isn’t enough to keep the cellulite off. BodyShape does the job.”
- “I had lost a significant amount of weight over a two-year period and had, as one would expect, an excess of skin. Despite my continued efforts, I was unable to remedy this situation and was convinced that my only option left would be ... plastic surgery. Hoping to avoid this, I tried BodyShape. I began using the product and was astonished with the results.... [W]ithin eight weeks, the concerns were but a distant memory.”
- “I have been using BodyShape for about three months (twice a day) and I absolutely love it! The cellulite on my thighs has been reduced by at least 50%....”
- “[T]he cellulite on my inner and outer thigh is gone!”

Fast-Acting Wrinkle Reducer

- The product name implies structure/function effect to reduce skin wrinkling.
- Internet web site, www.hydroderm.com
 - “This anti-aging skin serum helps reduce wrinkles and fine lines”
 - “This fast acting wrinkle serum utilizes its patented Collagen Infusion Delivery System to deliver full collagen molecules to the skin, a feat previously available only by injection.”
 - “Hydroderm scientists developed the unique Collagen Infusion Delivery System, a transdermal formula that actually delivers whole collagen molecules directly to the skin....”
 - “Vyo-Serum helps support the new collagen....”
 - “[P]rovides the skin with,..whole collagen molecules that help restore and rejuvenate your skin’s essential material.”
 - “Vyo-serum works as an instant lifting serum and active anti-aging ingredient.”

- “[D]uring an independent clinical study, Hydroderm reduced wrinkled [*sic*] length and thickness by a combined 63.5%....”
- “Life Extension magazine published an independent report on Hydroderm, attesting to its wrinkle-reducing effects.”
- “[D]ermatologists have recommended Hydroderm as an alternative method of decreasing fine lines and wrinkles.”
- (quoting article from *Life Extension* magazine) “Finally, ... there was a topical liquid that produced many of the effects of injections without the pain and huge expense.”
- (quoting article from *Life Extension* magazine) “Hydroderm has demonstrated efficacy in reversing the signs of certain aspects of skin aging....”
- “Researchers noticed visible age-reversing effects, including a reduction in fine lines, diminished bags under the eye, and removal of irregular pigmentation.”
- “Hydroderm may reduce wrinkle length and width nearly by a combined 50%....”
- “Hydroderm’s patented Collagen Infusion Delivery System...delivers entire, intact collagen molecules and encourages quick and dynamic skin rejuvenation.”
- (quoting article from *Life Extension* magazine) “[C]ollagen molecules are delivered directly to ... the epidermis - an effect achieved previously only by injection.”
- “This formula produces a dramatic, visible improvement by providing whole collagen molecules that can restore and revive wrinkled, aged skin.”
- “One woman who regularly used Botox® injections stated that Hydroderm™ worked just as well.”

Your website also includes claims in the form of testimonials. Some examples are as follows:

- “I was considering plastic surgery. But now I don’t have to.”
- “I do have all the tattletale signs of aging. And old products that don’t work. But this truly does work. ... It’s the only anti-aging product I now use.”

Anti-Aging Eye Complex

- The product name implies structure/function effect to protect against and counteract skin damage that results from skin aging.
- Internet web site, www.hydroderm.com
 - “Puffiness, Swelling, Dark Circles? Anti-Aging Eye Complex helps turn back the clock for the delicate skin around your eyes. This time-released serum helps reduce inflammation and encourages a constant flow of oxygenated blood to the eye area to reduce dark circles and puffiness under the eyes.”
 - “Anti-Aging Eye Complex is a unique serum that diminishes the effects of aging in the delicate skin around your eyes.”
 - “MgCl [an ingredient in the product] acts as a vasodilator to open up blood vessels....”

- "Tocopherol [an ingredient in the product]: protects skin from the damaging effects that result from exposure to UV rays, pollution, and harsh airborne elements."
- "Jojoba esters [an ingredient in the product]: reduces puffiness and dark circles."
- "Witch hazel [an ingredient in the product]: eases skin inflammation."
- "Anti-Aging Eye Complex is perfect for crow's feet as well as dark circles."

Intense Oil-Free Facial Moisturizer

Internet web site, www.hydroderm.com

- "Employing the universal botanical soother Aloe vera, this formula provides healing support to worn out skin. Legendary for its ability to help the body recover from injury, Aloe actually promotes restoration of the skin, fostering strong ties between your inner skin fibers."

These claims cause your products Body Shape Cellulite Toning Lotion, Fast-Acting Wrinkle Remover, Anti-Aging Eye Complex, and Intense Oil-Free Facial Moisturizer to be drugs as defined in section 201(g)(1)(C) of the Act [21 USC 321(g)(1)(C)]. Because your products are not generally recognized as safe and effective for the above referenced uses, the products are also new drugs as defined in section 201(p) of the Act [21 USC 321(p)]. Under section 505 of the Act (21 USC 355), a new drug may not be legally marketed in the U.S. without prior approval from FDA.

Your booklet entitled "body shape: cellulite reduction cream" includes structure/function claims for several of your other products (Fast-Acting Wrinkle Remover, Anti-Aging Eye Complex, and Intense Oil-Free Facial Moisturizer) similar to claims quoted from your website above. That booklet is additional evidence that those products are drugs because they are intended to affect the structure or function of the body.

This letter is not intended to be an all inclusive review of your products and their labeling. 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 and injunctions against the manufacturer and/or distributor of illegal products.

In addition to the violations described above, we also note that the label of Body Shape Cellulite Toning Lotion declares its ingredients in two separate sections "Main Ingredients" and "Other Ingredients." This separate declaration is repeated on your Internet web site. The separate listing of "main" and "other" ingredients is inappropriate for a product marketed as a cosmetic. Cosmetic ingredients must be listed on the product label either in descending order of predominance (see 21 CFR 701.3(a)) or grouped as specified in 21 CFR 701.3(f).

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.

Your reply should be sent to the attention of Compliance Officer Jennifer Thomas, US Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway (HFS-607), College Park, Maryland 20740.

Sincerely,

for 
Joseph R. Baca
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition