DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 331-4902

WARNING LETTER

Via Fed-Ex

April 24, 2007

File # 07-NWJ-11

Ms. Randi Schinder
President
Fusion Brands International SRL
1339 Wellington Street, Suite 203
Ottawa, ON, Canada K1Y 3B8

Dear Ms. Schinder:

This letter is in reference to your firm's marketing and distribution of your LiftFusion ™ brand products, Micro-injected M-Tox ™ Transdermal Face Lift, Mini Micro-injected M-Tox ™ Transdermal Face Lift, and Micro-injected M-Tox ™ Transdermal Eye Lift. The Food and Drug Administration (FDA) has reviewed your Internet web site at http://www.fusionbeauty.com and http://liftfusion.com/ (also accessible through http://www.wrinkle-reducer.com/) and the labeling for these products, including the literature that accompanies these products 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:

- "The first Topical-Injectable™ alternative to doctor-administered anti-wrinkle injections: proven more effective than Botox® in a clinical study."

- "LiftFusion™, a Topical-Injectable™ with...active ingredients, helps reduce existing wrinkles AND boost collagen to promote skin's natural defenses against new ones."

- "M-Tox™ formula features patented nanosphere technology that delivers a powerful blend of anti-aging elements to actively counteract fine lines and deep wrinkles."

- "LiftFusion's™ ...wrinkle-repairing results are...measurably proven better than Botox® in a clinical comparative study."

- "Until now, eliminating lines and wrinkles effectively has required painful, costly and regular injections of muscle inhibitors like Botox® and fillers like Restylane®.... LiftFusion™ formula...delivers immediate, visibly transformational results...without the discomfort, side effects and unnatural loss of facial expressiveness associated with many syringe-administered anti-wrinkle products."

- "Hyaluronic acid-filling spheres capture and instantly swell with the body's water, plumping to fill and smooth even deep wrinkles, smoothing and lifting to restore skin's youthful firmness"

- "[V]ertical and horizontal forehead furrows, frown lines, crow's feet + nasolabial lines are...repaired."

- "[B]locks muscle contractions within 10 minutes of application to the skin which helps prevent new lines and wrinkles from forming."

- "Nanospheres –spheres that deliver Mtox by relaxing muscles..."

- "Mtox helps to prevent new wrinkle from forming by reducing repetitive facial muscle contractions."

As stated above, these claims cause your LiftFusion™ products to be drugs. Because these products are not generally recognized among qualified experts as safe and effective for the above referenced uses, the products are also new drugs as defined in section 201(p) of the 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.

Even if all drug claims were removed from labeling for the LiftFusion™ products, your labels' failure to accurately identify the manufacturer, packer or distributor and include the business address would cause the products to be misbranded cosmetics under Section 602(b)(1) of the Act [21 USC 362(b)(1)]. , Cosmetic labels must specify the name and place of business of the manufacturer, packer or distributor (See 21 CFR 701.12) Further, when the cosmetic is not manufactured by the firm named on the label, it must be accompanied by a qualifying phrase which states the firm's relation to the product,

e.g., "manufactured for" or "distributed by." Your product labels merely state "FusionBeauty, Inc., Boca Raton, FL 33433." FDA was unable to locate a business presence for your firm in Boca Raton. Your labels should accurately declare your firm's place of business. And since you do not currently manufacture the products listed above, a qualifying phrase such as "distributed by" should be included preceding of the name of your firm.

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

You should take prompt action to correct any violations, including the violations identified in this letter. Failure to do so may result in enforcement action without further notice. The Act authorizes injunctions against manufacturers and distributors of illegal products and seizure of such 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 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.

Please send your reply to the Food and Drug Administration, Attention: Richard Manney, Compliance Officer, at U.S. Food and Drug Administration, 10 Waterview Boulevard, Parsippany, New Jersey.

If you have questions regarding any issues in this letter, please contact Mr. Manney at (973) 331-4908.

Sincerely,

Douglas I. Ellsworth
District Director
New Jersey District

[redacted]