Inspections, Compliance, Enforcement, and Criminal Investigations

Lifetech Resources LLC 4/18/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506
Telephone: 949-608-2900
FAX: 949-608-4415

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 32-11

April 18, 2011

Mr. Richard Carieri
Lifetech Resources LLC
9540 Cozycroft Ave
Chatsworth, CA 91311

Dear Mr. Carieri:

This letter is in reference to your firm's involvement in the manufacturing, distribution, and promotion of RapidLash Eyelash Renewal Serum ("RapidLash"), NeuLash Active Eyelash Technology ("NeuLash"), and NeuveauBrow Active Eyebrow Technology ("NeuveauBrow"). As presently formulated, labeled and promoted, these products violate provisions of the Federal Food, Drug, and Cosmetic Act (the Act). As described below, "RapidLash", "NeuLash", and "NeuveauBrow" are unapproved new drugs in violation of sections 505(a) and 301(d) of the Act (21 U.S.C. §§ 355(a) and 331(d)) and misbranded drugs in violation of section 502 (21 U.S.C. §§ 352) of the Act. Furthermore, because "RapidLash", "NeuLash", and "NeuveauBrow" are intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance, they also are cosmetics within the meaning of section 201(i) of the Act (21 U.S.C. § 321(i)) and misbranded under section 602(a) of the Act (21 U.S.C. § 362(a)). In addition, "RapidLash" and "NeuLash" are adulterated cosmetics under section 601(a) of the Act (21 U.S.C. § 361(a)).

Unapproved New Drug and Misbranded Drug

"RapidLash", "NeuLash", and "NeuveauBrow" are promoted for growth of eyelashes and eyebrows in labeling on various websites including http://www.RapidLash.com, http://www.NeuLash.com, and http://www.NeaveauBrow.com and in promotional literature about the products. Examples of these claims include, but are not limited to, the following:

RapidLash

- (website) "After 84 days of daily use, RapidLash induced a significant increase in the length of eyelashes"
- (website video) "This formula is designed to lengthen and thicken lashes in 30 days. Your lashes and your eyebrows grow thicker and faster."
- (website video) "RapidLash, which is this eyeliner type stuff that you paint on your eyes, and your lashes grow. . ."
- (website video) "There are brands like RapidLash that really grow your lashes."
- (website) "When I reached about age 50, my eyelashes had seemed to shrink to nothing and wearing

mascara was senseless. Then along came Rapid Lash! I began to notice a change with my eyelashes in less then 4 weeks of using it. In 6 weeks, my eyelashes were back to the original length of my younger days."
• (website audio) "…I have been using RapidLash for probably going on three months now, and let me tell you this stuff is awesome. . . .My eyelashes have grown . . .."
• (promotional pamphlet) "I went to the salon and they asked me if I wanted my eyebrows trimmed. I never had any eyebrows before RapidLash"

NeuLash

• (website) "I lost my eyelashes during chemotherapy and had none for three years. When I heard about products to help lengthen and thicken lashes, I was skeptical but chose to try neuLash because of its great customer reviews. . .. After eight weeks, my lashes were curlier, darker, longer, and thicker than ever before."
• (magazine image from website) "NeuLash®, an active eyelash technology strengthens and lengthens eyelashes in as little as two weeks."
• (website) "Helps promote cell regeneration"

NeaveauBrow

• (promotional pamphlet) "Helps accelerate the length of the hair shaft, while promoting fuller, thicker, and healthier looking brows."
• (promotional pamphlet) "neuveauBrow [sic] features our exclusive **(b)(4)** which effectively renews and regenerates skin cells. . .."
• (website) "It took about 6 weeks for me too see anything, but, lo and behold, I looked in the mirror one morning and saw MANY new hairs filling in my brows. I could not believe it."
• (website) "It's easy to apply and you do get growth where you put it."

Based on the labeling and promotional materials described above, "RapidLash", "NeuLash", and "NeuveauBrow" are drugs as defined by sections 201(g)(1)(C) of the Act (21 U.S.C. §§ 321(g)(l)(B) and (C)) because they are articles intended to affect the structure or function of the body by inducing eyelash and eyebrow growth.

"RapidLash", "NeuLash", and "NeuveauBrow" as currently formulated, contain the active ingredient isopropyl cloprostenate. Isopropyl cloprostenate is a synthetic prostaglandin analog in the same class of compounds as the active ingredients in FDA-approved drugs indicated to lower intraocular pressure in glaucoma patients (e.g., **(b)(6)** (bimatoprost ophthalmic solution), **(b)(6)** (travoprost ophthalmic solution) and to treat hypotrichosis[1] of the eyelashes (e.g., **(b)(6)** (bimatoprost ophthalmic solution)). Prostaglandin analogs are well known to have an effect on the structure or function of the body.[2] The presence of the prostaglandin analog, isopropyl cloprostenate, along with appearance claims such as "enhance the appearance of your lashes and brows," "fuller healthier-looking lashes," and "fuller healthier-looking brows" indicate that your products are intended to affect the structure or function of the body.[3] Accordingly, "RapidLash", "NeuLash", and "NeuveauBrow" are drugs as defined by section 201(g)(1)(C) of the Act (21 U.S.C. § 321(g)(l)(C)).

Moreover, "RapidLash", "NeuLash", and "NeuveauBrow" are new drugs, as defined by section 201(p) of the Act, (21 U.S.C. § 321(p)), because they are not generally recognized as safe and effective under the conditions prescribed, recommended, or suggested in its labeling. Under sections 301(d) and 505(a) of the Act (21 U.S.C. §§ 331(d) and 355(a)), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for the drug. Based on our information, you do not have an FDA-approved application on file for these drug products.

"RapidLash" and "NeuLash" are prescription drugs as defined in section 503(b)(1)(A) of the Act (21 U.S.C. § 353(b)(1)(A)), because, in light of their toxicity or other potentiality for harmful effect, the method of their use, or the collateral measures necessary to their use, they are not safe for use except under the supervision of a practitioner licensed by law to administer them. Specifically, isopropyl cloprostenate, the active ingredient in "RapidLash", and "NeuLash" may lower intraocular pressure. Patients using these products concurrently with intraocular pressure lowering medication should be closely monitored for changes to their intraocular pressure. Other potential adverse events associated with prostaglandin analogs for ophthalmic use include ocular irritation, hyperemia, iris color change, macular edema, ocular inflammation, and interference with glaucoma therapy. In addition, prostaglandin analogs for ophthalmic use are currently classified as Pregnancy Class C.[4]

According to section 502(f)(1) of the Act (21 U.S.C. § 352(f)(1)), a drug is misbranded if, among other things, it fails to bear adequate directions for its intended uses. "Adequate directions for use" means directions under which a layman can use a drug safely and for the purposes for which it is intended (21 C.F.R. § 201.5). Prescription drugs can only be used safely at the direction, and under the supervision of, a licensed practitioner. Therefore, for prescription drugs, it is not possible to write adequate directions for use by a layperson. FDA-approved prescription drugs that bear their FDA-approved labeling are exempt from the requirement that they bear adequate directions for use by a layperson (21 C.F.R. §§ 201.100(c)(2) and 201.115). Because there is no FDA-approved application for "RapidLash" and "NeuLash", their labeling fails to bear adequate directions for the intended uses, causing them to be misbranded under section 502(f)(1) of the Act (21 U.S.C. § 352(f)(1)).

Additionally, under section 502(a) of the Act, a drug is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the Act (21 U.S.C. § 321(n)) provides that, in determining whether an article's labeling or advertising "is misleading, there shall be taken into account (among other things) not only representations made or suggested . . . but also the extent to which the labeling or advertising fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual."

"RapidLash", "NeuLash", and "NeuveauBrow" are misbranded under section 502(a) because their labeling makes misleading statements regarding the product's safety and also fails to reveal material facts with respect to consequences that may result from the use of the product. Specifically, your product literature for "RapidLash" states, "Passed the Safety Status in the US and EU," your product literature for "NeuLash" states, "Safety Status in the US and EU – Passed," and your product literature for "NeaveauBrow" states "Safety Status in the US – Passed." However, as stated above, your products have not been approved by FDA based on safety and efficacy. In fact, FDA has determined that drug products in the same class as the active ingredient in "RapidLash", "NeuLash", and "NeuveauBrow" cannot be used safely without the direction, or under the supervision of, a licensed medical practitioner. Despite making a claim regarding safety, your products fail to include warnings about the possible adverse affects associated with the active ingredients used in your products. Thus, you have failed to reveal consequences that may result from the use of these products as described in the labeling, in violation of section 201(n) of the Act.

The introduction or delivery for introduction into interstate commerce of a misbranded product violates section 301(a) of the Act (21 U.S.C. § 331(a)).

Adulterated and Misbranded Cosmetic

Even if "RapidLash", "NeuLash", and "NeuveauBrow" were cosmetics within the meaning of section 201(i) of the Act (21 U.S.C. § 321(i)), they could not be lawfully marketed because they would be misbranded under section 602(a) of the Act (21 U.S.C. § 362(a)) and, in the case of "NeuLash" and "NeuveauBrow" adulterated under section 601(a) of the Act (21 U.S.C. § 361(a)).

Under section 602(a) of the Act (21 U.S.C. § 362(a)), a cosmetic is misbranded if its labeling is false or misleading in any particular. "RapidLash", "NeuLash", and "NeuveauBrow" are misbranded cosmetics under section 602(a) because, as discussed above, their labeling is misleading in that it fails to reveal facts material with respect to consequences that may result from the use of the products under the conditions of use prescribed in the labeling.

In addition, under section 601(a) of the Act (21 U.S.C. § 361(a)), a cosmetic is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or, under such conditions of use as are customary or usual. "RapidLash" and "NeuLash" are adulterated cosmetics under section 601(a) because they bear or contain a deleterious substance that may render them injurious to users under the conditions of use prescribed in their labeling. Specifically, "RapidLash" and "NeuLash" contain isopropyl cloprostenate which, under the conditions of use prescribed in the labeling, may cause the following injuries: ocular irritation, hyperemia, iris color change, macular edema, ocular inflammation, and interference with intraocular pressure reduction therapy. In addition, as mentioned above, prostaglandin analogs for ophthalmic use are currently classified as Pregnancy Class C; women of childbearing age are considered at risk for injury.

It is a violation of section 301(a) of the Act (21 U.S.C. § 331(a)) to introduce or deliver for introduction into interstate commerce any cosmetic that is adulterated or misbranded.

* * *

The issues and violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your product. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. Furthermore, please advise what actions you will take to address product that you have already distributed. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Please send your response to:

Attention: Blake Bevill
Director Compliance Branch
U.S. Food and Drug Administration
19701 Fairchild
Irvine, CA 92612

If you have any questions, please contact Dr. Raymond W. Brullo, Compliance Officer, at 949.608.2918 or raymond.brullo@fda.hhs.gov.

A description of the new drug approval process can be found on FDA's internet website at http://www.fda.gov/cder/regulatory/applications/default.htm. Any questions you may have regarding this process should be directed to the Food and Drug Administration, Division of Drug Information (HFD 240), Center for Drug Evaluation and Research, 10001 New Hampshire Ave., Silver Spring, MD 20903-1707.

Sincerely,

/s/

Alonza E. Cruse
District Director
Los Angeles District

[1] Hypotrichosis is another name for having inadequate or not enough eyelashes.
[2] For example, the FDA-approved labeling for **(b)(6)** notes that the products may change eyelashes, including "increased length, thickness and number of lashes.
[3] The intended use of a product may be determined by, amoug other things, its labeling, advertising, and the circumstances surrounding its distribution, 21 C.F.R. § 201.128.
[4] Drugs are classified as Pregnancy Category C when either (1) animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks; or (2) there are no animal reproduction studies and no adequate and well controlled studies in humans, 21 C.F.R § 201.57.