American Aesthetics Medical Supply, Inc. 9/23/13

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3128

September 23, 2013

Ref:2013-DAL-WL-048

WARNING LETTER

UPS OVERNIGHT MAIL

Mr. Quenin R. Blackwell
President and Owner
American Aesthetics Medical Supply, Inc.
d/b/a Aesthetics Medical, Inc.
3238 Towerwood Drive
Dallas, TX 75234-2315

Dear Mr. Blackwell:

During an inspection of your firm located in Dallas, Texas, on March 14 through 19, 2013, investigators from the United States Food and Drug Administration (FDA) determined that your firm promotes and markets Microderma S-100 Microdermabrasion System, Microdermabrasion Crystals, Youth 1 Microcurrent with LED Therapy, and BioLight. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

Your firm performs servicing of the Microderma S-100 Microdermabrasion System and repackages **(b)(4)** labeled as Microdermabrasion Crystals and marketed as an accessory to the MicroDerma S-100 Microdermabrasion System or other manufacturers' devices. Your firm also operates as a relabeler of the Microderma S-100 Microdermabrasion System, Youth 1 Microcurrent with LED Light Therapy, and BioLight devices marketed by your firm. These operations cause your firm to meet the definition of a manufacturer within the meaning of 21 CFR 820.3(o).

MEDICAL DEVICE REPORTING

Our inspection revealed that your firm's above-referenced devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting.

Significant violations include, but are not limited to, the following:

Failure to develop, maintain, and implement adequate written Medical Device Reporting (MDR) procedures, as required by 21 CFR 803.17.

Specifically, your firm did not have MDR procedures.

Unapproved Devices

A review of the marketing brochures, user manuals, training manuals, and instruction manuals collected during the inspection and your firm's website at http://www.aestheticsmedical.com for the above-referenced devices revealed that your firm has not received premarket clearance for the intended uses that are being marketing with these devices. Examples of these claims include:

SkinBorn Microderma S-100 Microdermabrasion System, page 4 of the training manual states:

- "Microdermabrasion enhances the skin by: …Healing active acne."

Youth 1 Microcurrent with LED Light Therapy:

Pages 2, 3, 4, and 6 of the instruction manual state:

- "Imagine the combination of LED light energy and microcurrent technology for complete photo-rejuvenation treatment with the most noticeable results in non-invasive skin care treatment…effectively tackle wrinkles, fine lines, and other aging skin concerns."

- "Red Light Stimulates fibroblastic activity to help the stimulation of collagen production. Clients get excellent results for treating wrinkles, enlarged pores, and swelling after surgery..."

- "Blue Light

Blue light frequency can get to the core of what causes acne eruptions and eventually kill the acne bacteria, while helping with the inflammation caused from the acne…"

- "Green Light

Most skin types react well to green light. Its wavelength achieves good result in evening-out pigmentation, smoothing fine lines and improving hydration. Good for capillary dilation and pigmented skin treatment."

- "Yellow Light

The yellow light effectively rejuvenates the epidermis by stimulating the production of collagen and elastin to slow the aging process. Good for brightening the skin tone, by treating hyper pigmentation."

- “Aesthetics Medical has designed and developed an entirely new state of the art esthetic system…a process that involves the use of four different lights that have been specifically designed to increase collagen levels, treat a wide range of dermatological conditions, such as acne, blemish, skin redness, wrinkle, actinic keratosis, non-melanoma skin cancers, skin rejuvenation, vitiligo, and wound healing post elective surgery.”

- "...Clinical studies have consistently shown that Micro Current causes the following:
  35% increase in blood circulation
  28% increase in lymphatic drainage
  45% increase in number of elastin fibers in your skin
  10% increase in collagen thickness in the dermis layer of your skin
  Various types of Micro Current modalities are commonly used in professional sports and Olympics to accelerate healing or soreness and injury..."

The brochure states:

- “Doctor Recommended, #1 Choice in leading spas…Photodynamic Cell Modulation…Highly effective adjunctive treatments for: Photo-Aging ● Post Surgical Scars and Post Peel Skin ● Hyperpigmentation ● Acne”

- “Microcurrent delivers gentle electrical frequencies that mimic the skin’s own electrical signals…These extremely low level electrical impulses result in:
  1. Muscle Reeducation…
  2. Increased Blood Circulation…
  3. Protein Synthesis and Membrane transport…
  4. Increased Collagen and Elastin production…
  5. Increased ATP (adenosine triphosphate)…
  6. Increase of Lymphatic Drainage…”

- “Red Light 640nm…Photo-Aging Adjunctive Treatment…”
- “Amber Light 590nm…Scar Healing Acceleration…”
- “Green Light 525 nm…Hyperpigmentation Adjunctive Treatment…”
- “Blue Light 470 nm…Acne Adjunctive Treatment…”

BioLight:

Pages 3 and 6 of the user manual state:

- “BioLight is a non-thermal light-based skin care device used to activate the skin’s natural rejuvenation process and repair damaged tissue…Noticeable improvements can be seen after a single treatment.
  Features and Benefits
  For the patient:
  Activates the skin’s natural skin rejuvenation process
  Heals damaged cells
  Reduction in the appearance of fine lines, brown spots, and freckles
  Dissolves red blotches
  Improves acne conditions…
  Minimizes appearance of scars…
  Treat large surface areas at one time, such as the entire face or chest…”

- “BioLight Color Chart…

The BioLight system also improves other medical, physical, and psychological conditions as indicated below.

Blue Light
Cosmetic Effect: Improves acne prone skin and skin irritations.
Medical Indication: Fever, migraine, sleep disorder, inflammations, redness and skin irritation, acne, herpes, allergies, sun burn, insect bites.

Green Light
Cosmetic Effect: Treats general skin problems, lessens the appearance of fine lines, wrinkles, and stress; promotes wound healing and lessens the appearance of scars.
Medical Indication: Weakened immune system, fresh wounds/scars, headaches, herpes (antiseptic effect), nervousness, tension.

Yellow Light
Cosmetic Effect: Stimulates skin metabolism, stabilizes irritated skin.

Medical Indication: Stomach aches and intestine complaints, depression, tiredness.

Red Light
Cosmetic Effect: Stimulates blood circulation, activates cell metabolism, revitalizes tired skin.
Medical Indication: Weak immune system, pain, blood circulation disorder, frostbite, rheumatism, exhaustion."

Your website at www.aestheticsmedical.com states:

- "BioLight

Non-thermal light-based skin care device used to activate the skin's natural rejuvenation process. The BioLight skin care process uses Light Emitting Diodes (LED) technology…Brings a glow to dull complexions…6X more powerful than conventional LED…"

Because of the above-referenced product claims, your Microderma S-100 Microdermabrasion System, Youth 1 Microcurrent with LED Light Therapy, and BioLight are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g). The devices are also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). For a device requiring premarket approval, the notification required by section 510(k) is deemed satisfied when a PMA is pending before the agency in accordance with [21 CFR 807.81(b)]. The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm. The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

Establishment Registration and Product Listing

Under section 510 of the Act (21 U.S.C. § 360), manufacturers of medical devices are required to annually register with the FDA. In September 2007, section 510 of the Act was amended by the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85) to require domestic and foreign device establishments to submit their annual establishment registration and device listing information to FDA by electronic means [section 510(p) of the Act (21 U.S.C. § 360(p))] during the period beginning October 1st and ending December 31st of each year. Our records indicate that your firm has not fulfilled annual registration and listing requirements for fiscal year 2013.

Therefore all of your firm's devices are misbranded within the meaning of section 502(o) of the Act (21 U.S.C. § 352(o)), in that the devices were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the Act (21 U.S.C. § 360) and were not included in a list required by section 510(j) of the Act (21 U.S.C. § 360(j)).

Unapproved Drugs

Your firm also markets and distributes the following products under your firm's own label name of SkinBorn, and promotes them on your website at http://www.skinborn.com: Super Antioxidant Cream, Beta & Alpha Hydroxy Acid, Perfect Face, Perfect Tone, Advanced Regeneration Complex, Medi-C Plus, Panthenol Soothing Mist, and Vitamin-A Antioxidant Therapy.

A review of the product labels and marketing brochures collected during the inspection and your firm's website in September 2013 revealed that these products are being marketed for uses that cause them to be drugs under sections 201(g)(1)(B) and/or section 201(g)(1)(C) of the Act, [21 U.S.C. §§ 321(g)(1)(B) and 321(g)(1)(C)].

The claims on your marketing brochures, product labels, and website indicate that these products are drugs because they are articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or articles intended to affect the structure or function of the body of man, rendering them drugs under the Act. The marketing of these products with claims evidencing these intended uses violates the Act.

Examples of structure/function claims observed in the products labeling and on the firm's website at www.skinborn.com that indicate intended physiologic or drug effects include, but are not limited to the following:

SkinBorn® Super Antioxidant Cream

- "Super Antioxidant…promotes cell growth, increase cellular turnover…healing acne and sun damaged skin… "
- "Panthenol (B-5) Aids in the healing process"
- "Vitamin D aids in the reproduction of new skin cells"
- "Vitamin E helps skin tissue to better process its oxygen supply"
- "Vitamin A builds elastin and aids in the production of collagen"
- "Pomegranate extracts…extending the life of fibroblasts"
- "Camellia Sinensis Leaf Extract (Green tea) –…guard against blemish formations…reduces sun damage to the skin…reduces inflammation, redness, irritation,…The anti-carcinogenic effects of green tea on the skin have been widely documented…its ability to speed wound healing…"

SkinBorn® Beta & Alpha Hydroxy Acid

- "Beta & Alpha Hydroxy Acid…A combination of Glycolic & Salicylic Acids provides antiseptic, anti-pruritic (stops itching & burning) and anti-fungal agents for treating ingrown hair and moderate to severe skin conditions…"
- "Antiseptic action reduces bacteria that promote acne"
- "Best for moderate to severe acne"

SkinBorn® Perfect Face

- "Antioxidants C, E, & CoQ10 repair cellular damage, increasing collagen and elastin production…"
- "Stimulates healthy Collagen production"

- “Anti-inflammatory”
- “Repairs and protects from sun damage…”

SkinBorn® Perfect Tone

- “A treatment gel that inhibits the production of melanin and lightens existing pigmentation, beneficial for sun-damaged and acne skins….”
- “Inhibits the production of melanin…”
- “Lightens existing pigmentation”
- “Lightens all hyper-pigmentation”
- “Inhibits the production of melanin, prevents hyper-pigmentation to worsen…”

SkinBorn® Advanced Regeneration Complex

- “Promotes production of Collagen and Elastin”
- “Diminishes hyperpigmentation… and acne”
- “Great treatment for…sun damaged, and acne skin…”

SkinBorn® Medi-C Plus

- “This active anti-aging serum is the newest Vitamin C formulation. It helps repair sun damaged skin… enhances collagen formation while improving elasticity. Plus, it inhibits melanosites to…even out skin tone”
- “Reduces hyper pigmentation”
- “Repairs the effects of sun damage…
- “Stimulates collagen levels”
- “Anti-inflammatory properties”

SkinBorn® Panthenol Soothing Mist

- “SkinBorn Panthenol Soothing Mist has healing properties, counteracting surface bacteria helping with acne, reduces inflammation, alleviates sunburns, soothes irritated skin and minor skin disorders.”
- “Stimulates cellular proliferation”
- “Wound healing”
- “Anti- Inflammatory”

SkinBorn® Vitamin A Antioxidant Therapy

- “…increasing collagen production”
- “Essential in the healing process and reduces healing time in acneic skin”
- “The product provides the same benefits of a retinoid without itching, flaking, redness, and irritation.”

Your products are not generally recognized among qualified experts as safe and effective for the above referenced uses and, therefore, the products are 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 U.S. without prior approval from FDA in the form of an approved New Drug Application (NDA). A description of the new drug approval process can be found on FDA's internet website at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm .

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm’s planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm’s response should be comprehensive and address all violations included in this Warning Letter.

Quality System Regulation

In addition, FDA has noted nonconformances with regards to section 501(h) of the Act (21 U.S.C. § 351(h)), which are deficiencies within your firm’s quality system pertaining to current good manufacturing practice requirements specified in the Quality System regulation found at 21 CFR Part 820.

We have not received your written response to our investigators’ observations noted on the Form FDA 483 (FDA 483), Inspectional Observations that was issued to you on March 19, 2013. These violations include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50.

Specifically, your firm does not have written purchasing control procedures for the Microderma S-100 Microdermabrasion System, bulk **(b)(4)**, and Youth 1 Microcurrent with LED Light Therapy. Additionally, your firm has not evaluated and documented the ability of the manufacturers of these products to meet specified requirements, including quality requirements.

2. Failure to establish and maintain adequate procedures for acceptance activities, including inspections, tests, or other verification activities. Acceptance or rejection shall be documented, as required by 21 CFR 820.80(a).

Specifically, your firm does not have written procedures to specify how the Microderma S-100

Microdermabrasion System, bulk **(b)(4)**, and Youth 1 Microcurrent with LED Light Therapy are received, inspected, or verified at your firm for acceptance or rejection. In addition, your firm does not have records of testing or inspection.

3. Failure to establish and maintain instructions and procedures for performing and verifying that the servicing meets the specified requirements, as required by 21 CFR 820.200(a).

Specifically, your firm has not established written procedures to define what servicing is needed for the Microderma S-100 Microdermabrasion and Youth 1 Microcurrent with LED Light Therapy devices, how they are serviced, repaired or returned to the manufacturers, and what and where test results are documented after servicing. For example, your firm serviced three Microderma S-100 Microdermabrasion devices as documented on Sales Invoice **(b)(4)** dated **(b)(4)**.

4. Failure to establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, evaluation, segregation, and disposition of nonconforming product, as required by 21 CFR 820.90(a).
Specifically, your firm does not have written procedures to define how nonconforming product is identified, evaluated, investigated, and dispositioned. For example, if a device cannot be repaired or serviced, your firm will return the device to its manufacturer. This process was not documented.

5. Failure to establish and maintain adequate complaint handling procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a).

Specifically, your firm has not established any written complaint handling procedures to address what information is considered complaints, sources of complaints, how complaints are documented upon receipt, and evaluation or investigation of complaints. For example, a review of your firm's sales invoices showed a number of the Microderma S-100 Microdermabrasion devices were serviced due to loss of suction or vacuum and microdermabrasion crystals not flowing properly. Although your firm replaced parts during servicing, it did not document evaluation or investigation of the probable causes of these complaints.

6. Failure to establish and maintain adequate procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100(a).

Specifically, your firm has not established written procedures for corrective and preventive actions to include the requirements for: indicating what sources of quality data is reviewed or analyzed, investigating the cause of nonconforming, identifying corrective or preventive actions needed to correct or prevent recurrence of nonconforming products or quality problems, and disseminating information on nonconforming products or quality problems or nonconforming to those directly responsible for assuring the quality of such product or prevention of such problems.

7. Failure to establish adequate procedures for identifying training needs and ensuring that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented, as required 21 CFR 820.25(b).

Specifically, your firm has not established written training procedures that define the training requirements for its employees, what specific training will be provided, and how training will be documented. Your firm has no records of employee training.

8. Failure to establish and maintain procedures for quality audits and conduct such audits to assure that the quality system is in compliance with established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22.

Specifically, your firm has not established any written procedures for quality audits of the operations it performed and has not conducted any quality audits.

Your firm's response should be sent to: Mr. Thao Ta, Compliance Officer, Dallas District Office, U.S. Food and Drug Administration, HFR-SW140, 4040 N. Central Expressway, Suite 300, Dallas, Texas 75204. If you have any questions about the contents of this letter, please contact: Mr. Ta at 214-253-5217.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems.

Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely
/S/
Reynaldo R. Rodriguez, Jr.
Dallas District Director

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