U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Genesis Biosystems, Inc 9/21/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Dallas District Office
4040 North Central Expressway
Suite 300
Dallas, Texas 75204-3128

September 21, 2015

2015-DAL-WL-32

WARNING LETTER

UNITED PARCEL SERVICE

James D. Lafferty, President
Genesis Biosystems, Inc.
1500 Eagle Court
Lewisville, Texas 75057

Dear Mr. Lafferty:

During an inspection of your firm located in Lewisville, Texas, on December 8, 2014 through December 16, 2014, and a recent inspection of your firm on June 1, 2015, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures and distributes the DermaFrac Micro-channeling System (DermaFrac System) and the Lipivage Fat Harvest and Transfer System (Lipivage). 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.

Our inspections, and review of materials collected during the inspections, revealed that the DermaFrac System is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because you do 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 (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). The DermaFrac

System is also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because you did not notify the Agency of your intent to introduce the device 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) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the Agency. 21 CFR 807.81(b). The kind of information you need to submit in order to obtain approval or clearance for your device is described on the Internet at **http://www.fda.gov/cdrh/devadvice/3122.html. (http://www.fda.gov/cdrh/devadvice/3122.html.)** The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

Specifically, FDA has reviewed product labeling for the DermaFrac System, including brochures and handouts, which revealed that the DermaFrac System is a dermal micro-channeling system that is designed expressly to drive topical solutions to penetrate deeper into the tissue. The DermaFrac System creates micro-channels to the dermoepidermal (DE) junction while simultaneously infusing topicals.

For example, FDA's review of the DermaFrac System's Unit Manual (DFR-MAN-001, Rev F), page 8, revealed the following description for this device:

> DermaFrac treatments allow for infusion of treatment-specific solutions using vacuum and micro-channeling treatment tips that provide a patient with results that are both immediate and long-term. These professional treatments allow for a fraction of the upper skin surface to have thousands of micro-channels created providing pathways through the stratum corneum and epidermis that take in the solutions that are dispensed simultaneously during the treatment. These solutions are formulated to address specific goals for skin conditioning as well as to optimize flow to the skin and the micro-channels that have been created.

Based on FDA's review of the documents collected during the above-referenced inspections, including our review of your firm's website, the DermaFrac System appears to consist of a stamp of needles that is controlled by a motor in order to make multiple controlled-depth penetrations perpendicularly into the skin while the operator moves the DermaFrac System across the skin surface.

In general, devices classified under 21 CFR 878.4820 (Dermabrasion Brush, Powered) are exempt from premarket notification. Generic devices of this type have abrasion substrates, which are brushes, rasps, and burrs that are intended to abrade and remove layers of the skin via shear force. Unlike the 510(k)-exempt powered dermabrasion brushes, the DermaFrac System is intended to achieve its clinical effect by penetrating the skin via "microchannels" and thus raises new questions of safety and effectiveness.

Because the safe ranges of needle lengths, penetration depths, and speeds of the device are unknown, FDA has safety concerns regarding the potential for the needles to damage vessels and nerves. Because the DermaFrac System employs a different fundamental scientific technology than the devices in 21 CFR 878.4820, it exceeds the limitations described in 21 CFR 878.9(b) and is not exempt from premarket notification.

Our office requests that Genesis Biosystems, Inc., immediately cease activities that result in the misbranding and/or adulteration of the DermaFrac System, such as the commercial distribution of the device for the uses discussed above.

The inspections also revealed that the DermaFrac System and Lipivage are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at 21 CFR Part 820. We received a response from your firm dated January 5, 2015 concerning our investigator's observations noted on the Form FDA 483 (FDA 483), Inspectional Observations, that was issued to your firm at the conclusion of the inspection. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to validate computer software for its intended use according to an established protocol when computers or automated data processing systems are used as part of production or the quality system, as required by 21 CFR 820.70(i).

For example, your firm uses the software **(b)(4)**, developed by **(b)(4)**, to document, maintain, and track customer complaints electronically. However, as stated by your firm's Director of Quality Assurance (QA) & Regulatory Affairs (RA) during the inspection, the software does not generate time-stamped audit trails to independently record the date and time of operator entries and actions that create, edit, or modify electronic records.

The adequacy of your firm's response cannot be determined at this time. Your firm indicated that it will evaluate the software to determine which data entries should be time-stamped or if a standalone software program should instead be purchased to replace the current system. You also stated that your firm would be working with a consultant to create testing protocols after software validation. However, no additional information could be provided because the corrective action was ongoing at the time of your FDA 483 response, and employees had yet to be retrained. We will verify the adequacy of this corrective action during our next inspection.

2. Failure to establish and maintain procedures to ensure that device history records (DHRs) for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record (DMR) and the requirements of this part, as required by 21 CFR 820.184.

For example, our investigator reviewed your firm's DHRs for the DermaFrac System device. Your firm did not maintain a representative label of the serial number label placed on the back of the DermaFrac System unit.

The adequacy of your firm's response cannot be determined at this time. Your response indicated that your firm's standard operating procedure, the Control of Quality Records (4040400-SOP-001), would be revised, and the correction would be documented under CAPA No. 034 and Change Request No. 1897. However, no additional information could be provided because the corrective action was ongoing at the time of your FDA 483 response, and employees had yet to be retrained. We will verify the adequacy of this corrective action during our next inspection.

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 (which must address systemic problems) 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.

In addition, your firm's listing for its Lipivage product identifies it as a class I device, exempt from premarket notification requirements under 21 CFR 880.6960 (Irrigating Syringe). Based on the limited information that FDA has on this product, we believe it is a medical device that appears to be regulated by the Center for Biologics Evaluation and Research and may require premarket review. To determine the appropriate regulation of this product, please contact Dr. Patrick Riggins, Director of the Regulatory Management Staff, Office of Cellular, Tissue, and Gene Therapies at (240) 402-8346.

Further, the labeling for the DermaFrac System states that it is to be used with topical solutions to penetrate deeper into the tissue. Products that meet the definition of a drug, as defined in section 201(g)(1)(B) and (C) of the Act, 21 U.S.C. § 321(g)(1)(B) and (C), regardless of whether they are also cosmetics, must comply with all applicable drug provisions of the Act and corresponding regulations in order to be legally marketed. Products that are intended as solely cosmetics should not include any claims or other information demonstrating drug intended uses.

Your firm's response to this letter should be sent to: Dallas District Office, ATTN: John W. Diehl, 4040 North Central Expressway, Suite 300, Dallas, Texas 75204. If you have any questions about the contents of this letter, please contact Mr. Diehl at 214-253-5288.

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

CC:
Tom Brinck, Manager

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More in 2015 (/ICECI/EnforcementActions/WarningLetters/2015/default.htm)