HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

94959d

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

AUG 16 2004

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Hubert Lee Cole
Chairman, CEO
Rejuvenu International, Ltd.
11832 US 15/501 South, Unit #2
Aberdeen, North Carolina 28315

Dear Mr. Cole:

During an inspection of your establishment located in Aberdeen, North Carolina, on December 16, 2003 through January 22, 2004, our investigators determined that your firm manufactures and distributes a hair removal system, marketed as the Super Phaser GOLD System and Transcutaneous Patch that uses tweezers, continuous transdermal probes or hands-free transcutaneous patches to remove hair. This product is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that the Super Phaser Gold System is adulterated under section 501(h) of the Act in that the methods used in, or the facilities or controls used for its manufacture, packing, storage, or installation are not in conformity with applicable requirements of section 520(f)(1)(A), and the Quality System Regulation, promulgated thereunder in Title 21, Code of Federal Regulations (CFR), Part 820. Significant violations include, but are not limited to, the following:

1. Failure to establish and maintain a quality system that meets the requirements of the Quality System Regulation, as required by 21 CFR 820.5. The inspection revealed that the firm has no quality system in place.

2. Failure to establish quality system procedures, instructions, and an outline of the structure of the documentation used in the quality system where appropriate, as required by 21 CFR 820.20(e). For example, the quality system procedures were not established, defined, documented, complete or implemented.

3. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this part and the manufacturer's established quality policy and objectives and to document the dates and results of quality system reviews, as required by 21 CFR 820.20(c). For example, your

firm does not have documentation of any formal management reviews.

4. Failure of management with executive responsibility to appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for:
   (i) Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part; and
   (ii) Reporting on the performance of the quality system to management with executive responsibility for review, as required by 21 CFR 820.20(b)(3).

   For example, a management representative has not been appointed to report to management on the performance of the quality system. You stated that you would become responsible for FDA related issues including establishing a quality system.

5. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. For example, management has distributed this device since the year 2000 and has never conducted an audit.

6. Failure to establish, maintain, and document procedures for implementing corrective and preventive action.

   (i) For example, your firm has not established and maintained any corrective and preventive action (CAPA) procedures as required by 21 CFR 820.100(a).
   (ii) In addition, your firm has no documentation of any actions taken to correct or prevent recurrence of nonconforming products and other quality problems as required by 21 CFR 820.100(b).

7. Failure to establish, maintain, and document procedures for acceptance activities, including inspections, tests, or other verification activities.

   (i) For example, your firm has no written formal procedures established for acceptance testing, as required by 21 CFR 820.80(a).

(ii) In addition, your firm does not document acceptance criteria tests that are performed upon receipt from the contract manufacturer and prior to distribution to the customer as required by 21 CFR 820.80(e).

8. Failure to establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants, as required by 21 CFR 820.50(a). For example, your firm uses several contractors and suppliers and none have been evaluated.

9. Failure to establish and maintain instructions and procedures for performing and verifying that servicing meets the specified requirements, as required by 21 CFR 820.200(a). For example, there are no formal procedures for the return, handling or repair of the Super Phaser Gold devices.

10. Failure to maintain complaint files and to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example, the firm does not have a formal system of complaint handling and no complaint file was available.

The inspection also revealed that your device is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your Super Phaser Gold User's Guide and literature state that this device is a needle-less unit and claim that the product offers the consumer three different methods for permanent hair removal via a galvanic current transmitted across the skin. The methods are as follows: Tweezers, Continuous Transdermal Probes, and Hands-free Transcutaneous Patches. Although the tweezers are exempt from premarket notification requirements under 21 CFR 878.5360, the probe and patch are not.

The Super Phaser Gold System with Transdermal Probes and Trancutaneous Patches is adulterated under section 501(f)(1)(B) in that it is a Class III device under section 513(f) and does not have an approved application for premarket approval in effect pursuant to section 515(a), or an approved application for an investigational device exemption under section 520(g).

The device is also misbranded under Section 502(o) in that a notice or other information respecting the new intended use of the device was not provided to the FDA as required by section 510(k) and 21 CFR 807.81(a)(3)(ii). The Center for Devices and Radiological Health (CDRH) has not cleared patch or probe epilators for any indication.

For a product requiring premarket approval before marketing, the notification required by section 510(k) of the act is deemed to be satisfied when a premarket approval application (PMA) is pending before the agency, 21 CFR 807.81(b).

In 1995, American Hair Removal Systems, a company you were previously affiliated with, submitted a 510(k) [redacted] for the AHRS Surface Electrolysis System, a modified patch epilator device that you apparently understood to require FDA clearance. However, CDRH's Office of Device Evaluation (ODE) had numerous unanswered questions and could not clear the device. Your device applies diffuse energy to the site, whereas needle and tweezer epilators apply directed energy. CDRH's ODE indicated a new protocol should be developed and sent you a [redacted] letter, notifying you that your submission was being withdrawn from the system and that all information should be re-submitted. FDA received no response to that notification.

Subsequently, absent FDA clearance, you marketed the device along with claims that the device is FDA cleared or approved. Appropriate data has not been submitted to support claims of no risk of infection, changes of pigmentation, no bruising, no scabbing, or no scarring, or that the procedure is painless. We have requested evidence to support these claims on several occasions but no information has been received from your firm.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483, issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations, identified by the FDA. You must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Additionally, no premarket submissions for Class III devices to which this Quality System regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also no requests for Certificates to Foreign Governments will be approved until the violations related to the subject device have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to, actions for seizure, injunction and/or civil money penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Please address your response to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement A, General Surgery Devices Branch, HFZ-323, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Fred R. Rangel.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Mr. Fred Rangel, at the same address or by telephone at 301 594-4618 or FAX 301 594-4636.

Sincerely yours,

Larry D. Spears for

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health