



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MD160n

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 30 1998

Warning Letter

via Federal Express

Mr. James C. Fallon
Chief Operating Officer
Derma Genesis, Inc.
26081 Merit Circle, Building #115
Laguna Hills, California 92653

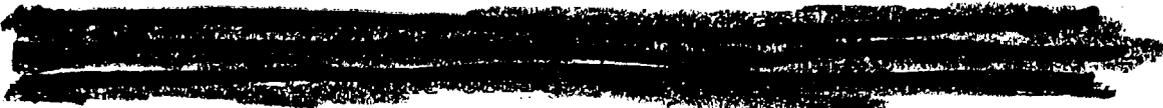
Dear Mr. Fallon:

It has come to our attention that your firm, Derma Genesis, Inc., has been commercially distributing Derma Peel dermabraders without receiving marketing clearance from the Food and Drug Administration (FDA). Dermabraders are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Because your firm does not have a cleared premarket notification, section 510(k), from FDA, marketing this device is a violation of the law. Therefore, Derma Peel dermabraders are adulterated under section 501(f)(1)(B) of the Act, in that they are class III devices under section 513(f) and do 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 520(g).

Derma Peel dermabraders are misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the devices was not provided to the FDA as required by section 510(k).

For your information, the Food and Drug Administration Modernization Act of 1997 (FDAMA) that went into effect February 19, 1998, provided for the exemption of certain class I medical devices by FDA. In the section "Limitations on Exemptions" in the Federal Register dated January 21, 1998, (Volume 63, Number 21, page 5388), it explains that the exemption only applies to class I devices which are substantially equivalent to other class I devices already cleared or exempt. The Derma Peel dermabrader has not been shown to be substantially equivalent to a legally marketed device.



3 lines purged

9 lines

[REDACTED]

4 lines

[REDACTED]

Your firm continues to distribute the Derma Peel dermabraders to both leasing companies as well as purchasers without obtaining marketing clearance.

In your letter to Mr. Anthony Watson, ODE, dated October 13, 1998, you erroneously state that the Derma Peel dermabrader "was converted from its 510(k) status to that of a Class I device ... because it was used for the same indications as previous devices." You should be aware that dermabraders were already class I medical devices; therefore, I assume you meant an exempt class I device due to the FDAMA. Nevertheless, Mr. Watson never stated nor implied, either orally or in writing, that the Derma Peel dermabraders would be exempt from 510(k) clearance; substantial equivalence to exempt devices has not been demonstrated, as expressed in his February 11, 1998, letter.

Further, in your October 15, 1998, letter to Mr. Watson you refer to a phone conversation held on February 19, 1998, stating that Mr. Watson told you that certain products were being reclassified as exempt and would not need 510(k) clearance. However, Mr. Watson did not tell you that your device, the Derma Peel dermabrader, was now exempt; on the contrary,

4 lines

[REDACTED]

This letter is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Act and regulations. 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.

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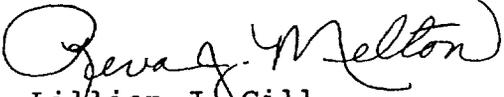
Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar

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.

You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers' Assistance at phone number: 1-800-638-2041, FAX: 301-443-8818, or through our Internet website at <http://www.fda.gov>.

Please submit your response to Ms. Adrienne Galdi, Director, Division of Enforcement I (HFZ-323), Office of Compliance, Center for Devices and Radiological Health, at the letterhead address. If you have any questions, please call Ms. Cory Tylka of the General Surgery Devices Branch at (301) 594-4595 ext. 170, or FAX: (301) 594-4636.

Sincerely yours,

for/ 
Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

*Purged
11/3/98 CEST*