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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Mid-Atlantic Region

Telephone (201) 331-2910

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

June 30, 1997

WARNING LETTER

CERTIFIED MAIL-
RETURN RECEIPT REQUESTED

Mr. Samuel Mann
President
Inverness Corp.
17-10 Willow Street
Fairlawn, New Jersey 07410

RELEASE

REMOVED BY [Signature]
C.O. 7/1/97
DATE

FILE NO.: 97-NWJ-41

Dear Mr. Mann:

During an inspection of your firm located at the above address between March 4 and March 13, 1997, our investigators documented deviations from Medical Device Reporting (MDR) regulations (21 CFR 803) and from medical device cGMP regulations (21 CFR 820) in conjunction with your firm's manufacture of ear piercing and electrolysis equipment, causing them to be misbranded within the meaning of Section 502(t)(2) of the Federal Food, Drug and Cosmetic Act (the "Act") and adulterated within the meaning of Section 501(h) of the Act as follows:

MDR

1. Your firm failed to develop, maintain, and implement written MDR procedures.
2. Your firm failed to submit Medical Device Reports to the FDA for complaints that required medical intervention and/or which caused permanent impairment of a body function or permanent damage to a body structure or function. For example,
 - A. Complainant [Redacted], dated 4/30/96, who received small burns and permanent scarring on both of her legs, subsequent to using the "One Touch" electrolysis product.
 - B. Complainant [Redacted], dated 3/22/96, who suffered irritation and scarring on her chin after utilizing the electrolysis device.

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- C. Complainant [REDACTED], dated 9/11/95, who suffered scarring on her ankles and abdomen area, subsequent to utilizing your "One Touch" electrolysis kit.
- D. Complainant [REDACTED], dated 8/26/96, required medical intervention to have her earring surgically removed because the earring had worked its way into the piercing and into her ear.
- E. Complainant [REDACTED], event occurring on 3/03/95, developed a severe infection which required surgery and caused cosmetic disfigurement, after having his left ear pierced.
- F. Complainant [REDACTED], dated 1/25/96, developed an infection after ear piercing, which was confirmed by a VA physician. The patient was admitted to the hospital and was administered antibiotics.

In addition to the above listed events, several other complaints involving your ear piercing system are MDR reportable under 21 CFR 803.50(a)(1). These include complaint [REDACTED], dated 6/13/96, complaint [REDACTED], dated 4/09/96, and complaint [REDACTED], dated 11/13/95, all of which developed an infection and were treated with antibiotics.

CGMP

- 3. Your firm failed to review, evaluate and investigate (or to document your decision not to investigate) customer complaints and/or MDR reportable events. Your firm has attributed these failures to user error without conducting an investigation.
- 4. Your firm failed to provide documentation for bioburden monitoring, package integrity and device functionality testing.
- 5. Your firm does not have a written procedure for conducting quality audits.
- 6. There are no written procedures for in-house nor for contracted calibration services conducted for your measuring and testing equipment.

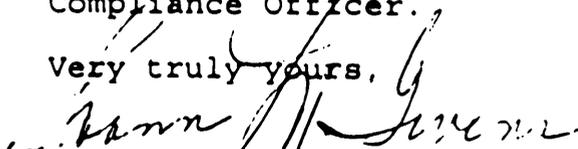
The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the good manufacturing practice regulations. Until these violations are corrected, Federal agencies will be informed that FDA recommends against the award of contracts for affected products.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These include civil penalties, seizure and/or injunction.

You should 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.

Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Boulevard, Third Floor, Parsippany, New Jersey 07054, Attention: Vincent P. Radice, Compliance Officer.

Very truly yours,


Joann M. Givens
Acting District Director
New Jersey District Office

VPR:slw