



DEPARTMENT OF HEALTH & HUMAN SERVICES

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482

11/24/97

Public Health Service
Cincinnati District

Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202-1097

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

November 5, 1997

**Warning Letter
CIN-WL-97-581**

Charles Francisco, President
Victoreen, Inc.
6000 Cochran Road
Cleveland, Ohio 44139

Dear Mr. Francisco:

During an inspection of your firm located at the above address on August 11-18, 1997 our Investigator determined that your firm manufactures Precision Electrometer/Dosemeters. They are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act). The Inspection revealed that your devices are adulterated in that, the methods used in, or the facilities or controls used for manufacturing, packaging, storage, or installation are not in conformance with the Good Manufacturing Practice Regulations (GMP) for Medical Devices specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

Failure to establish and implement an adequate complaint handling system. Although the computerized complaint system used by your firm allows input from all departments, there is no system in place to assure that all service records are reviewed and evaluated for potential inclusion in the complaint handling system.

For example, on April 1996 an internal "Victoreen, Inc. Complaint Report" was logged into your complaint system to describe a high rate of devices that were returned for service and found by your firm to exhibit cracked resistor networks. The failure of this component could allow the Model 530 and Model 530SI Precision Electrometer/Dosemeters to display incorrect readings when exposed to radiation. There is no documentation that each of these returned devices was investigated as a complaint.

Furthermore, even after your customers were notified of the potential problem with the resistor network in the Precision Electrometer/Dosemeters, devices returned to your firm for corrective action [redacted] but of [redacted] had the resistor network replaced with a more durable component, but there was no examination of the replaced resistor networks to determine if they were cracked.

A complaint which opened on October 29, 1996 concerned a high percentage of Model 530 Electrometer/Dosemeters returned for service because of front end "blow outs". [redacted] of [redacted] repairs done between [redacted] to [redacted] were to replace the FET and FET protector because of front end blow out. There is no documentation that any of the individual service repair incidents were investigated as complaints.

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Failure to adequately investigate the failure of a device to meet performance specifications after a device has been released for distribution, and to make a written record of the investigation including conclusions and follow-up.

For example, there were no records of failure investigations for the Model 530 and Model 530SI Electrometer/Dosemeters that were returned for service because of the problem with cracks in the resistor network or the problem with front end "blow out".

Failure to validate quality assurance tests.

A test procedure entitled "Model 530 Calibration Select Switch Test" was made available to customers who purchased Model 530 and Model 530SI Precision Electrometer/Dosemeters as part of the corrective action the customers could take to determine whether the resistor network is cracked in their Electrometer/Dosemeter. This test procedure was never validated.

Additionally, the FDA inspection revealed that your devices are misbranded within the meaning of Section 502(t)(2) of the Act, in that your firm failed to furnish material or information required by or under Section 519 and the Medical Device Reporting (MDR) Regulation, 21 CFR Part 803, as follows:

Failure to develop, maintain, and implement written MDR procedures, as required by 21 CFR §803.17.

Failure to report within 30 days of becoming aware of information that reasonably suggests that your device malfunctioned and would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as required by 21 CFR § 803.50(a)(2). For example, a reportable malfunction that your firm became aware of in April 1996 was not reported until March 1997.

Failure to establish and maintain MDR event files which include all documentation of the deliberations and decision-making processes used to determine if a device-related death, serious injury or malfunction was or was not reportable, as required by 21 CFR § 803.18(b)(1)(i). For example, there is no documentation of the deliberation conducted in April 1996, to determine whether the failure of the resistor network that could allow the Model 530 to display incorrect readings represented an event which must be reported to the FDA.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the ACT and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the FDA 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. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions.

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 devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

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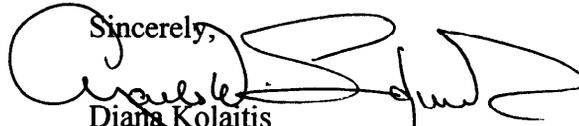
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by The Food and Drug Administration without further notice. Possible actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We acknowledge that you have submitted to this office a response concerning our investigator's observations noted on the form FDA 483. We have reviewed your firm's letter of response to the investigator's observations and have concluded that it is inadequate. Detailed comments on your response are in an FDA letter to Ms. Linda S. Nash, Director, Regulatory Affairs & Q.A., Victoreen, Inc.. A copy of our letter to Ms. Nash is enclosed.

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 fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202.

Sincerely,



Diana Kolaitis
Acting District Director
Cincinnati District

Enclosure