



DEPARTMENT OF HEALTH & HUMAN SERVICES

M 357H

Public Health Service  
Mid-Atlantic Region

*5/6/97*  
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Telephone (201) 331-2909

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

April 24, 1997

**WARNING LETTER**

Mr. George Mulvaney  
Robbins Instruments, Inc.  
2 North Passaic Avenue  
Chatham, New Jersey 07928

**File No: 97-NWJ-32**

Dear Mr. Mulvaney:

During an inspection of your firm located at 2 North Passaic Avenue, Chatham, New Jersey, on March 31 and April 2, 1997, our Investigators determined that your firm manufactures the Dermo-Jet, a needleless high pressure injector. The Dermo-Jet 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 this device is considered adulterated within the meaning of Section 501(h) of the Act, in that manufacturing and related quality assurance activities are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal regulations (CFR), Part 820, as follows:

1) Your firm's complaint handling system and failure investigation documentation is deficient, for example:

○ Service records reviewed for Dermo-Jet units 11708, 11759, 10906, 10923 and 11763 document malfunctions which are related to the reliability, safety, effectiveness and/or performance of these devices. These service records were not evaluated as product complaints. Units were repaired and/or replaced without further review or documented investigation of device failure.

2) There is no verification that components, which could adversely affect device performance, are inspected, sampled and tested to assure conformance to specifications, for example:

○ Service record for unit 11708 indicates probable cause of failure was a short main spring. The procedure to visually inspect incoming components was discontinued two years ago.

**RELEASE**

REVIEWED BY Mulvaney 4/29/97  
C.O. DATE

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3) Device History Records are deficient, for example:

○ Assembly records are not complete for Dermo-Jet units 11742, 11710 and 11737 in that there is no documentation that these units were inspected, rejected or released by a member of the Quality Assurance Unit.

4) There is no documentation that repaired or reprocessed units have been tested to assure they conform to release specifications.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA483 issued at the close out of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. Review of your firm's inspectional history indicates that deficiencies regarding complaint handling procedures and failure investigations have been previously cited. 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.

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. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

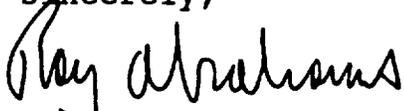
Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. 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.

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Your response should be sent to the New Jersey District Office,  
Food & Drug Administration, 10 Waterview Blvd., 3rd Floor,  
Parsippany, New Jersey 07054, Attn: Mercedes B. Mota, Compliance  
Officer.

Sincerely,



RAY ABRAHAMS  
Acting District Director  
New Jersey District

**CERTIFIED MAIL -**  
**RETURN RECEIPT REQUESTED**

MBM:np