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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED *PK*

September 11, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97 - 62

Franklin Pass, M.D.
Chairman and CEO
Medi-ject Corporation
161 Cheshire Lane, Suite 100
Minneapolis, Minnesota 55441

Dear Dr. Pass:

During an inspection of your firm located at the above location on August 19-22 and 26, 1997, Investigator Philips determined that your firm manufactures a needle-free insulin injection system. These needle-free injection systems are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act). The above stated inspection revealed these devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used for manufacturing these devices are not in conformance with the Good Manufacturing Practices (GMPs) for Medical Devices as specified in Title 21, Code of Federal Regulations (CFR), Part 820 as follows:

1. There are no formal complaint handling procedures.
2. There are no formal criteria for the types of reports which must be handled as complaints.

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3. Several complaints have been received that have not been investigated, documented and filed in a separate complaint file.
4. Returns of needle-free syringes have not been handled under your Returned Goods procedure.
5. Your calculations to determine the failure rate of your needle-free syringes appear to be erroneous.
6. Several product failure investigations were incomplete.

Please refer to the Form FDA-483 issued on August 26, 1997, for a more complete listing of the deficiencies noted during this inspection.

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 FDA-483 issued at the close-out 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 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 pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until these violations have been corrected. Also, no requests for product export certificates 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 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

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explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to insure that similar violations will not recur. If corrective actions cannot be completed within 15 working days, please state the reason for the delay and the time within which the corrections will be completed.

Your response may be directed to Compliance Officer Thomas P. Nelson at the address indicated on the letterhead.

Sincerely,

A handwritten signature in cursive script that reads "James A. Rahto".

James A. Rahto
Director
Minneapolis District

TPN/ccl