



PURGED

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

December 20, 1999

xc: HFI-35
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 00 - 13

Patrik F.A. De Haes, M.D.
President and Chief Executive Officer
Disetronic Medical Systems, Inc.
5151 Program Avenue
St. Paul, MN 55112

Dear Dr. De Haes:

We are writing to you because on November 19 and 23, 1999, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the insulin infusion pumps and accessories that are manufactured in your Burgdorf, Switzerland, facility and imported into the United States by your firm in St. Paul, Minnesota.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. Insulin infusion pumps are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). Because your Minnesota facility is an initial importer of the devices you are responsible for maintenance of the complaint system, Medical Device Reporting (MDR), general record keeping, and performance of failure investigations as required by your operating procedures.

Our inspection found that the devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in, facilities or controls used for manufacturing, packing, storage, or installation of the medical devices are not in conformance with the Good Manufacturing Practices (GMP) requirements set forth in the Quality System Regulations for Medical Devices as prescribed by Title 21, Code of Federal Regulations, Part 820 (21 CFR 820).

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Our inspection found your products are in violation of the law because of:

1. Failure to establish and maintain procedures for implementing corrective and preventive action (CAPA), [21 CFR 820.100] in that:
 - a. Returned devices were not evaluated per appropriate specifications [21 CFR 820.100(a)(1)].
 - b. CAPA procedures addressing the investigation of the cause of non-conformities relating to product, processes, and the quality system were not established in that there is no document that contains the current specifications used to evaluate the check point of the returned devices [21 CFR 820.100(a)(2)].
 - c. Procedures addressing the investigation of the cause of non-conformities relating to product, processes, and the quality system were not followed [21 CFR 820.100(a)(2)]. Specifically, management's review of the Trend Analysis Report was not being evaluated, documented, and forwarded to [REDACTED] as required by the firm's own complaint procedure.
2. Failure to document management's review and approval and the effective dates of changes made to the checkpoint procedures used to conduct your preliminary complaint evaluation of returned infusion pumps [21 CFR 820.40(a)].
3. Complaint handling procedures were not established and maintained to ensure that all complaints are processed in a timely manner [21 CFR 820.198(a)(1)].

In legal terms, the products are adulterated under Section 501(h) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As CEO, the most responsible individual at Disetronic Medical Systems, Inc., it is ultimately your responsibility to ensure that devices imported by your facility in St. Paul, Minnesota, are in compliance with each requirement of the Act and regulations.

The specific violations noted in this letter and in the form 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 the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

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You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts. Additionally, no pending applications for pre-market approval (PMAs) or export approval requests will be approved and no pre-market notifications [Section 510(k)] will be found to be substantially equivalent for products manufactured for your facility until the violations have been corrected.

Please let this office know in writing within 15 working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Compliance Officer Howard E. Manresa at the address indicated on the letterhead.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of current Good Manufacturing Practices for your devices and does not necessarily address other obligations you have under the law. 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 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Mr. Manresa at (612)334-4100 ext. 156.

Sincerely,


James A. Rahto
District Director
Minneapolis District

HEM/ccl

Enclosure: FDA-483, 11/23/99