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

June 12, 1997

cc: HEI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-46

Thomas J. McGoldrick
President and CEO
Minntech Corporation d.b.a. Renal Systems
14905 28th Avenue North
Plymouth, MN 55447

Dear Mr. McGoldrick:

We are writing to you because on May 28 through June 3, 1997, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the product known as "BC-1 Bicarbonate Concentrate Powder", a dialysate that is made and marketed by your firm.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), this product is considered to be a medical device because it is used to diagnose or treat a medical condition or to affect the structure or function of the body. Dialysate is a medical device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). It is classified as a Class II, critical device.

The law requires that manufacturers of medical devices adhere to Current Good Manufacturing Practice (CGMP) regulations for Medical Devices as specified in Title 21, Code of Federal Regulations (CFR), Part 820 in the methods used in, facilities or controls used for manufacturing, packing, storage, or installation of medical devices.

Page Two

**Thomas J. McGoldrick
June 12, 1997**

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

The powder dispensers used in the manufacture of the product have not been qualified or validated [21 CFR 820.100(a)(1)].

Weights of each component (sodium chloride and sodium bicarbonate) are not measured during production (21 CFR 820.160).

The Device History Records (DHR's) denote that powder dispensers #s 1 & 2, which had been shutdown due to erratic operation since April 9, 1997, were used in the May 14-19, 1997 production of lot C7028 [21 CFR 820.100(b)].

The DHR's lack documentation of reasons for rejecting product (21 CFR 820.161).

Written procedures do not address use of the _____ scale that is used in production 21 CFR 820.100 (b).

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

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.

The specific violations noted in this letter and in the FDA-483 issued at the closeout 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.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As president, the most responsible individual at Minntech Corp. d.b.a. Renal Systems, it is

Page Three

Thomas J. McGoldrick
June 12, 1997

ultimately your responsibility to ensure that devices manufactured at your facility in Plymouth, MN are in compliance with each requirement of the Act and regulations.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (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 Howard E. Manresa, Compliance Officer, Food and Drug Administration, 240 Hennepin Avenue, Minneapolis, MN 55401.

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,



Jim Roberts
Acting District Director
Minneapolis District

HEM

Enclosures: FDA-483 dated 6/3/97