



August 19, 1998

Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863

WARNING LETTER  
CHI-36-98

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Shan Padda, CEO  
Sabratek Corporation  
5601 West Howard  
Niles, IL 60714

Dear Mr. Padda:

During an inspection of the Niles, Illinois facility of Sabratek from July 13 to 24, 1998, Investigator Tamara Alicea determined that Sabratek is a manufacturer of infusion pumps. Infusion pumps are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR) as specified in Title 21, Code of Federal Regulations, Part 820, as follows:

1. Failure to identify the actions needed to correct and prevent recurrence of non-conforming product. For example, it was determined that the [REDACTED] had a software problem which prevented the infusion rate from exceeding the bolus rate while operating in the "PCA" mode. While the software has been revised, the software development process was not reviewed to prevent this type of problem from recurring.
2. Failure to ensure that changes to specifications, processes or procedures are verified or where appropriate validated, before implementation. For example, there was no documentation of the verification or validation that the change to the software (referenced above) was effective. Also, there was no verification or validation that the addition of urethane coating to the CPU board was effective.
3. Failure to maintain a procedure for the identification, documentation, and validation or where appropriate, verification, review and approval of design changes before their implementation.

4. Failure to investigate complaints involving pumps which did not meet accuracy specifications. For example, complaint numbers 9800357, 9801141, 9801305, 9802218, and 9802345, involved reports of the [REDACTED] not meeting its accuracy specifications. The pumps were recalibrated by the service department. These complaints were not investigated to establish a root cause of the performance problem. Also, there was no documentation that an investigation for this type of problem had been previously made and there was no written rationale for why no investigation was appropriate.

Also, for your information, 21 CFR Section 803.50 requires manufacturers to report within 30 days whenever the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer may have caused or contributed to a death or serious injury. According to Section 803.3(d), "Caused or contributed means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result" of failure, malfunction, improper or inadequate design, manufacture, labeling or user error.

This letter is not intended as 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 Form FDA 483 (enclosed) issued to Mr. Stephen L. Holden, President, 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.

We acknowledge receipt of Mr. Edward Waddell's response to our Form FDA 483, dated August 11, 1998. We remain concerned by the apparent lack of investigation to complaints as explained above in number 4. All other responses appear adequate.

Until FDA has documentation to establish that all corrections have been made, Federal agencies will be 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.

You should take prompt action to correct these deviations. Failure to correct these deviations may result in regulatory action being initiated by the FDA 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. We request that you provide an additional response to our concerns regarding lack of investigations of complaints (number 4).

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Your response should be sent to Stephen D. Eich, Compliance Officer, Food and Drug Administration, 300 South Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

Sincerely,

\s\  
Raymond V. Mlecko  
District Director

Enclosure

cc: Mr. Stephen Holden, President  
Sabratek Corporation  
5601 W Howard St  
Niles, IL 60714

cc: Mr. Edward Waddell  
Director of Quality Assurance  
Sabratek Corporation  
5601 W Howard St  
Niles, IL 60714