

HFI-35 11/97

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DEPARTMENT OF HEALTH & HUMAN SERVICES  
Food and Drug Administration  
New England District

Food and Drug Administration  
One Montvale Avenue  
Stoneham, Massachusetts 02180  
(781)279-1675 FAX: (781)279-1742

**WARNING LETTER**

December 12, 1997

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

NWE-08-98

K. Shan Padda  
Chief Executive Officer  
Sabratek Corporation  
5601 West Howard  
Niles, IL 60714

Dear Mr. Padda:

During an inspection conducted between August 28 and September 29, 1997 of your firm located in Woburn, MA, our Investigators determined that prefilled intravenous flush syringes are manufactured at this site. These products 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 the manufacturing, packing, storage, or installation of these devices are not in conformance with the Quality System Regulation for Medical Devices, as specified in Title 21 of the Code of Federal Regulations, Part 820 (21 CFR 820). You must comply with all requirements applicable to the operations in which you are engaged. The deficiencies noted by our Investigators include the following:

1. Failure to validate the aseptic filling process, in order to provide assurance that sterility of the final product has been maintained. For example:
  - a. An adequate validation study based on sterile media-fills has not been conducted.
  - b. There has been no surface sampling of the critical areas within the [REDACTED] workbench.
  - c. The effectiveness of procedures for the cleaning and sanitizing of workspaces has not been documented.
2. Failure to establish an adequate environmental control program. For example:
  - a. Routine air sampling is performed only on a [REDACTED] basis.
  - b. Gauges for temperature/humidity and pressure had not been calibrated from September 1995 to September 1997.
  - c. Within the last six months, there have been multiple instances of temperature and pressure readings beyond specified ranges, without documented explanations or corrective actions.
3. Failure to establish adequate acceptance activities. For example:
  - a. Saline flush syringes (Lot 5001-0507-1234 / Exp. 11/7/97 and Lot 5001-0516-1027 / Exp. 11/16/97) labeled as a 1 ml fill in a 3 ml syringe were distributed overfilled to 3 ml.
  - b. Incoming products (syringes, Heparin Injection, Saline Injection) are not tested.
  - c. Suppliers of incoming product are neither audited nor under any written agreement.
  - d. Finished product is not subject to any testing.

These devices are also adulterated within the meaning of Section 501(f)(1)(B) of the Act in that they are class III devices under Section 513(f) and do not have an approved

application for premarket approval in effect pursuant to Section 515(a), or an approved application for investigational device exemption under Section 520(g).

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 the regulations. The specific violations noted in this letter and the Form FDA 483 issued at the close of the inspection may be indicative 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-related, 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 requests for Certificates to Foreign Governments 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 FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We have received the letter dated October 10, 1997 from Steven Richard, which responds to the list of inspectional observations (Form FDA 483) issued at the close of the inspection. It is currently under review. Corrective actions presented in that response may be referenced, as appropriate, in your reply to this letter. Please include any available supporting documentation.

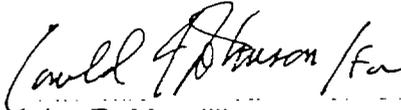
Please notify this office within fifteen (15) working days of the receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying system problems necessary to assure that 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.

Your response should be sent to:

Mark Lookabaugh  
Compliance Officer  
U.S. Food and Drug Administration  
One Montvale Avenue, 4th Floor  
Stoneham, MA 02180

If you have any questions concerning this matter, please contact Mr. Lookabaugh at 781.279.1675 x118.

Sincerely,



John R. Marzilli  
Director  
New England District Office

cc:

Elliott Mandell, President  
Rocap Division of Sabratek  
5601 West Howard  
Niles, IL 60714

Steven Richard, Senior Vice President  
Rocap Division of Sabratek  
Division Headquarters  
1629 Prime Court, Building 100  
Orlando, FL 32809

Neil Desautels, Director of Plant Operations  
Rocap Division of Sabratek  
5 Constitution Way  
Woburn, MA 01801

bcc:

HFA-224  
HFC-210 (include CFN: 12,24788), HFC-240 (include CFN)  
HFI-35 (purged, *signed*)  
HFZ-300  
HFZ-333 (Carolyn Niebauer, OAK4: 301.594.4618 x111)

MCL, GTC  
C/File (12,24788), R/File, LR/File, WL/File  
HFR-NE12, HFR-NE200, HFR-NE245 (purged)

State of Massachusetts (Grant Carrow)

HFR-SE240 (ORL-DO)  
HFR-MW140 (CHI-DO)

NWE-DO: JRM / GTC / DHE / MCL: mcl : 27 October 1997  
Revised: MCL: mcl 27 October 1997

*DA* *CA* *ML*  
NWE-DO: JRM / GTC / MCL: mcl: 12 December 1997  
Final revision: MCL: mcl 12 December 1997

*a:\warning\rocap.rvf [DISK SEVEN (7) 1997]*  
*final revision according to 9 Dec 1997 memo of concurrence from CDRH / OC / DOE II / GHDB*