



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

*HFI-35M34301*

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

**WARNING LETTER**

**FEB 22 2000**

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Gary Chilcott, President  
Sure-Way Systems, Inc.  
310 E. Harry Bridges Boulevard  
Wilmington, CA 90744

W/L 29-00

Dear Mr. Chilcott:

During an inspection of your facility conducted on January 10, 13 and 14, 2000, our investigator determined that your firm manufactures, reprocesses and distributes reusable sharps containers. These products are 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 Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and implement a quality policy which defines the intentions and direction of your organization with respect to quality [21 CFR 820.20(a)].
2. Failure to establish and implement a quality plan which defines the quality practices, resources, and activities relevant to devices designed and manufactured by your firm [21 CFR 820.20(d)].
3. Failure to establish and implement procedures for a systematic, independent examination of your quality system at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with the quality system procedures [21 CFR 820.22].

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4. Failure to establish and implement procedures to control the design of your device in order to ensure that specified design requirements are met [21 CFR 820.30(a)].
5. Failure to establish and implement procedures to control all documents required by the Quality System Regulation [21 CFR 820.40].
6. Failure to establish and implement procedures to ensure that all purchased or otherwise received product and services conform to specified requirements [21 CFR 820.50].
7. Failure to develop, conduct, control, and monitor production processes to ensure your devices conform to their specifications [21 CFR 820.70 & 75]. Specifically, your firm has no documented evidence which provides a high degree of assurance that your cleaning processes for your reusable devices used as part of production meet their pre-determined specifications and quality attributes. Most disturbing is that our investigation disclosed instances where equipment used in the washing decontamination process for reusable sharp containers did not meet their specified requirements and no investigations were conducted. Additionally, your firm has no schedules for the adjustment, cleaning and other maintenance activities for your cleaning equipment.
8. Failure to establish and implement procedures for acceptance of incoming product, in-process product and finished device acceptance to ensure that each product run or lot of finished device have met its acceptance criteria [21 CFR 820.80].
9. Failure to establish and implement procedures to ensure that device history records for each batch, lot or unit are maintained to demonstrate that the device was manufactured in with the Device Master Record and Quality System Regulation [21 CFR 820.184]. Specifically, your firm does not maintain any records describing the date of manufacture, quantities manufactured, quantities released, or the acceptance records.
10. Failure to establish and implement procedures to ensure that all complaints are processed in a uniform and timely manner [21 CFR 820.198].

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 form 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 violation identified by the 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 premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no request for Certificates For

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Products For Export 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 Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunctions, 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 explanation of each step being taken to identify and make corrections to any underlying systems 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 reply should be sent to Thomas L. Sawyer, Director, Compliance Branch and a copy to Dannie E. Rowland, Compliance Officer at U.S. Food and Drug Administration, 19900 MacArthur Boulevard, Suite 300, Irvine, California 92612-2445.

Sincerely,

  
Acting District Director

cc: State Department of Public Health  
Environmental Health Services  
Attn: Chief Food and Drug Branch  
601 North 7th Street, MS-357  
P.O. Box 942732  
Sacramento, CA 94234-7320