



**VIA FEDERAL EXPRESS**

**Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751**

**WARNING LETTER**

FLA-00-29

February 10, 2000

Carlos M. Campos, President & CEO  
Safety Disposal System, Inc.  
1100 25<sup>th</sup> Street, Suite 7B  
West Palm Beach, Florida 33407

Dear Mr. Campos:

We are writing to you because on January 10 through 18, 2000 FDA Investigator Bill Tackett, Jr. inspected your facility and collected information that revealed serious regulatory problems involving your firm's reprocessing of medical devices (reusable sharps containers).

Under the Federal Food, Drug, and Cosmetic Act (the Act), the products that your firm reprocesses are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers conform to the Quality System (QS) regulations for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that devices that you sort and clean for further reprocessing 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 their manufacture, packing, storage, or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

**QS Regulation/GMPs**

1. Failure to establish a quality policy as required by 21 CFR 820.20. For example, there is no written policy establishing the objectives for and commitment to quality (FDA 483, Item #1).

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2. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system pursuant to a defined schedule to ensure the quality system meets the requirements of the established quality policy and objectives as required by 21 CFR 820.20(c). For example, no reviews have been conducted to determine the effectiveness or suitability of the quality system (FDA 483, Item #2).
3. Failure to establish procedures for quality audits and conduct of audits to assure the quality system is in compliance with the established quality system requirements and the effectiveness of the quality system as required by 21 CFR 820.22. For example, no internal quality audits have been conducted (FDA 483, Item #3).
4. Failure to validate the processes for cleaning and sanitizing reusable sharps containers as required by 21 CFR 820.75. For example, no validation has been conducted (FDA 483, Item #7).
5. Failure to establish a complaint handling system as required by 21 CFR 820.198. For example, no procedures have been established or are maintained for receiving, reviewing and evaluating complaints by a formally designated unit (FDA 483, Item #4).
6. Failure to establish and maintain procedures for acceptance of incoming new product and product being returned for reuse as required by 21 CFR 820.80. For example, no acceptance activities are conducted including inspection, tests or other verification of activities involving condition, cleaning and sanitation (FDA 483, Item #6).
7. Failure to establish and maintain procedures for the calibration, adjustment or maintenance of process equipment as required by 820.70(g). For example, no inspections were conducted pursuant to your own procedures, which require a daily inspection of the Reusable Container Wash and Disinfection System (FDA 483, Item #8).
8. Failure to establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications as required by 21 CFR 820.70(a). For example, there are no procedures available describing the current washing system in use (FDA 483, Item #11).

The specific QS/GMP violations noted in this letter and in the List of Observations (FDA 483) issued to Peter A. Light, Chief of Operations 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.

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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 awards of contracts.

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, injunction, and/or civil penalties.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

A handwritten signature in black ink that reads "Reva J. Melton". The signature is written in a cursive style with a large initial "R" and "M".

Reva J. Melton  
Acting Director  
Florida District