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

HAND-DELIVERED

WARNING LETTER

FLA-00-34

March 7, 2001

Carlos M. Campos, President
Safety Disposal System, Inc.
6175 N.E. 153rd Street, suite 324
Miami Lakes, Florida 33014

Dear Mr. Campos:

During an inspection of your establishment located in West Palm Beach, Florida on January 10-12 & 16, 2001, FDA Investigator Michelle S. Dunaway determined that your establishment is a specification developer, reprocessor and distributor of reusable sharps containers, a medical device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Under the Federal Food, Drug, and Cosmetic Act (the Act), the product(s) that your firm manufactures/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 above-stated inspection revealed that this device is 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/reprocessing, packing, storage, or installation are not in conformance with the Quality System regulations for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

QS Regulation/GMPs

1. Your firm failed to establish a policy and objectives for, and commitment to, quality that management with executive responsibility shall ensure is understood, implemented, and maintained at all levels of the organization as required by 21 CFR 820.20. For example, the plant manager responsible for the supervision of the sharps container quality system, and individuals performing sharps container reprocessing have not been trained and are unfamiliar with the Quality System requirements. Your quality policy has not been implemented. Corrections to these observations were promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item # 1) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item #s 1-3).
2. Your firm failed to conduct management reviews covering the overall suitability of your quality system as required by 21 CFR 820.20(c). For example, the only area of the reprocessing operation that has been reviewed is the container washing area on May 4, and June 28, 2000. Corrections to this observation were promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item # 2) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item # 4).
3. Your firm failed to conduct quality audits that address all quality system requirements as required by 21 CFR 820.22. For example, the only areas of the reprocessing system that have been audited were the container washing area including the number of containers washed and rejected. Corrections to these observations were promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item # 3) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item #5).
4. Your firm failed to establish and maintain procedures for implementing corrective and preventive action as required by 21 CFR 820.100. Correction to this observation was promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item #s5 & 9) and Warning Letter #FLA-00-29 issued on February 10, 2000. The same observations were again made and issued to your firm on January 18, 2000, which was listed on the Inspectional Observations (FDA 483, Item # 15).

5. Your firm failed to validate the cleaning and disinfection processes of the reprocessing operation as required by 21 CFR 820.75(a) & (c). For example, the current process was implemented only three months ago, which replaced germicidal soap with an unspecified level of chlorine/bleach and changed the temperature of the wash from 180°F to an uncontrolled temperature range. It was also determined during the inspection that the water heater coil had been broken for three months and had not been replaced. The temperature of "hot" water was observed to be 65°F. Correction to this observation was promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item # 7) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item # 6).
6. Your firm failed to establish complaint handling procedures and there is no record that a failure investigation was conducted of a confirmed complaint required by 21 CFR 820.198. For example, a rack of sharps containers were released without being cleaned and no documented investigation was made. Correction to this observation was promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item #s 4 & 11) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item #s 7 & 10).
7. Your firm failed to establish and maintain written acceptance criteria for reprocessed sharps containers to ensure that each production run, lot, or batch of reprocessed devices meets acceptance criteria as required by 21 CFR 820.80(d). For example, leakage, physical condition, lid closeability and labeling are not included in the criteria for release. There is no specified sampling plan and acceptance activities are not documented unless one or more containers are rejected. A field examination of released sharps containers revealed one container that had rust colored stains on the lid opening, one container had an approximate quarter sized hole just below the lid, and at a minimum, five containers were missing the removable sliding door. Correction to this observation was promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item #6) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item #s 9 & 12).

8. Your firm failed to establish and maintain procedures for the current cleaning and disinfection processes as required by 21 CFR 820.70(a), (b). For example, chlorine and water temperature levels are not specified, controlled or monitored. Chlorine levels on January 11 and 12, 2000 were observed to be below 0.5ppm and the washer temperature to be 100°F and 70°F later and 200 ppm and 70°F, respectively. Correction to this observation was promised in your responses dated April 4 and July 5, 2000 to the Inspectional Observations (FDA 483, Item #11) dated January 18, 2000 issued to your firm during the previous inspection of your facility and to Warning Letter # FLA-00-29 issued to you dated February 10, 2000 (FDA 483, Item #10).
9. Your firm failed to establish and maintain procedures to prevent contamination of equipment or product substances that could reasonably be expected to have an adverse effect on product quality as required by 21 CFR 820.70(e). For example, an individual responsible for handling disinfected sharps containers was observed to be using gloves that had been used during the lid cleaning process that had a visible rust colored substance. Cloth towels are reused by laying them or tying them to a large fan. These towels are used for an unspecified or unknown number of day's production. The restrooms for workers do not have hot running water and there was nothing available for drying hands except for toilet paper (FDA 483, Item #11).
10. Your firm failed to maintain device history records (DHR's) to ensure that each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with specifications listed in the device master record (DMR) as required by 21 CFR 184. For example, employees marked the "Daily Protocol Parameter Log" for approximately three months, while the water heater coil was broken, "Yes" reporting the water temperature was 180°F even though the temperature was observed to be 100°F or below. These logs were reviewed and maintained by the Plant manager (FDA 483, Item #13).
11. Your firm failed to ensure that each DMR is prepared and approved as required by 21 CFR 820.181. For example, the DMR fails to include device and labeling specifications that address the useful life of sharps containers and the level required to effect disinfection (FDA 483, Item #16).

The specific violations noted in this letter and in the List of Observations (FDA 483) issued to Jorge Barroso, Plant Manager, 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.

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 Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contract, and to resume marketing clearance, and export clearance for products manufactured at your facility, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that they have conducted an audit of your firm's manufacturing and quality assurance systems relative to the requirements of the device QS regulation/GMPs (21 CFR Part 820). You should also submit a copy of the consultant's report, and your certification that you have reviewed the consultant's report and that your firm has initiated or completed all corrections called for in the report.

The initial certifications of audit and corrections and subsequent certifications of updated audits and corrections (if required) should be submitted to this office by the following dates:

- Date and certification of initial audit by consultant and firm (to be conducted within four (4) months of the receipt of this letter).
- Monthly reports and timeline of progress to achieve compliance to be submitted by the last day of each month until all corrective actions have been corrected not to exceed 4 months.
- Final certification of accomplished corrective and preventive actions related to this Warning Letter to be submitted no later than June 30, 2001.
- An annual certification and a report of an annual audit by an outside consultant for each of the next two years covering your firm's current status with regard to the Quality Systems regulation.

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. Any further distribution of this product is made on your own responsibility.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) 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.

You should also advise your intention to continue or cease distribution of the product in writing, until your firm's level of compliance with the Quality System regulation can be verified by the FDA .

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 cursive script, appearing to read "Emma Singleton".

Emma Singleton
Director, Florida District