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CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

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

**WARNING LETTER**

**FLA-04-42**

September 15, 2004

Jerry J. Flatt, President  
The Soule Company, Inc.  
4322 Pet Lane  
Lutz, Florida 33559-6349

Dear Mr. Flatt:

During an inspection of your establishment located at 4322 Pet Lane, Lutz, Florida on June 15 through 18, 2004, FDA Investigator Bill Tackett, Jr. determined that your firm manufactures the Rapid Foam product and other Styrofoam™ products for use in radiation therapy and positioning of patients in linear particle accelerators, which are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), [21 U.S.C. 321(h)].

The investigator documented significant violations from the Quality System (QS) Regulation, Title 21, Code of Federal Regulations (CFR), part 820 and the Medical Device Reporting Regulations, part 803. These violations cause the devices you manufacture to be adulterated within the meaning of Section 501(h) [21 U.S.C. 351(h)] and misbranded within the meaning of Section 502(t)(2) [21 U.S.C. 352(t)(2)] of the Act.

The investigator noted the following violations of the QS regulations:

1. Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality and is understood, implemented, and maintained at all levels of the organization as required by 21 CFR 820.20, (a), (b)(3)(i), and (d). Your firm has not established and implemented Quality System Regulation requirements including: CAPA procedures, Quality Audit procedures, Management Review procedures, Design Control procedures, and a Quality Policy and Plan (FDA 483; Item #1 - 4).
2. Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance

with the established quality system requirements and to determine the effectiveness of the quality system as required by 21 CFR 820.22. Your firm has not established quality audit procedures and has failed to conduct quality audits (FDA 483; Item #s 15 & 16).

3. Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action as required by 21 CFR 820.100(a). Your firm lacks procedures to analyze quality data, investigating causes of non-conformities, verifying/validating corrective and preventive actions, and the dissemination of information to responsible personnel (management) including: quality data related to complaints, in-process failures, receiving inspections, product returns, and quality audits (FDA 483, Item #5, 10 & 17).
4. Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications and all changes in specifications are verified/validated as required by 21 CFR 820.70(a) & (b). Your firm lacks procedures and failed to maintain production records documenting the manufacture of the Rapid Foam product and a change in the expiration date for the Rapid Foam kits was extended beyond the chemical manufacturer's expiration date without any documented verification/validation (FDA 483; Item #7, 8 & 9).
5. Each manufacturer shall maintain complaint files and maintain and establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit and shall include the nature and details of each complaint as required by 21 CFR 820.198(a) & (e)(5). Your firm failed to maintain and establish all requirements of the complaint handling system (FDA 483; Item #11-13).
6. Each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results and all activities are documented as required by 21 CFR 820.72(a). Your firm lacks procedures to ensure that equipment is calibrated according to a specified schedule and that all activities are properly documented (FDA 483; Item #18 & 19).
7. Each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met as required by 21 CFR 820.30(a). Your firm has failed to establish procedures to control the design process of your devices (FDA 483; Item #6).

Medical Device Reporting (MDR)

Your devices are misbranded within the meaning of section 502(t)(2) in that there was a failure to comply with a requirement prescribed under section 519 of the Act respecting the device as follows:

8. Manufacturers shall develop, maintain, and implement written MDR procedures for the timely and effective identification, communication, and evaluation of events that may be subject to medical device reporting requirements as required by 21 CFR 803.17(a)(1). Your firm's written medical device reporting procedures have not been implemented (FDA 483, Item #14).

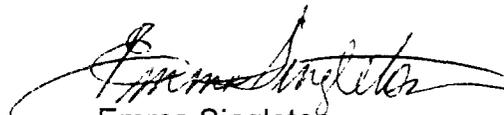
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

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. 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 to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps that you are still in the process of taking to correct the noted violations, including (1) the time frames within which the corrections will be completed, (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.

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,



Emma Singleton  
Director, Florida District