



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

d/2006b

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-70

August 20, 1998

Mr. James Balloun
Chairman of the Board
National Service Industries, Inc.
1420 Peachtree N.E.
Atlanta, Georgia 30309

Dear Mr. Balloun:

We are writing to you because on July 27 through 29, 1998, FDA Investigator R. Kevin Vogel collected information that revealed serious regulatory problems involving surgical gowns and operating room towels, which are processed and distributed by your firm, NPAC Sterile Processing located in St. Petersburg, Florida.

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

The inspection revealed that your 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 manufacture, packing, storage, or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

- Failure to adequately validate your firm's sterilization processes, e.g., a BI failure in August of 1997 and the device history record (DHR) was not available for review; empty chamber qualifications have not been completed for sterilizer #1 since 1992 and for sterilizer #2 since 1994; performance revalidation has not been

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completed since 1994; and sterilization revalidation as a result of changes in CSR packaging was not completed to assure the device was not adversely affected and that it continues to meet specifications.

- Failure to train and qualify individuals responsible for the CSR wrap folding procedure to assure consistency and that product meet specifications.
- Failure of your firm's purchasing controls to assure that suppliers can consistently provide gowns that meet appropriate specifications, e.g., water resistance, and to verify supplier's certificates of conformance.
- Failure to include audit schedules and criteria in your written Quality Assurance audit procedure, and your firm has failed to complete any internal Quality Assurance audits.
- Failure to have and implement a management review procedure that assures that the established quality policy and objectives are met.
- Failure to have and implement a corrective and preventive action procedure to identify existing and potential causes of nonconforming product.

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 FDA-483 issued to you 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 awards of contracts. Additionally, no premarket submissions for 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.

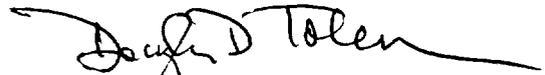
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

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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 timeframes within which the corrections will be completed, (2) any documentation indicating the correction has 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,

A handwritten signature in black ink, appearing to read "Douglas D. Tolen", with a long horizontal flourish extending to the right.

Douglas D. Tolen
Director, Florida
District