



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
g3736d

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

December 10, 2002

Ref: 2003-DAL-WL-07

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Gerald M. Benstock
Chairman and Chief Executive Officer
Superior Uniform Group, Inc.
10099 Seminole Blvd.
Seminole, Florida 33772

Dear Mr. Benstock:

We are writing to you because during an inspection of your firm, Eudora Garment Division of Superior Uniform Group, Inc., located at 304 Superior Drive, Eudora, Arkansas 71640, on August 19 through 21, 2002, a Food and Drug Administration (FDA) investigator determined that your establishment is a manufacturer of various styles of surgical OR (operating room) gowns, surgical drapes and accessories, and sterilization wraps. Based on the inspectional findings you are considered to be a manufacturer of medical devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Under the Act, the products you manufacture are considered to be class II medical devices. The law requires that manufacturers of medical devices obtain marketing clearance for their products from the FDA before they may offer them for sale. The law also requires that manufacturers submit to the FDA registration and listing information for each of their manufacturing sites. These documents should identify the company as a manufacturer. The stated submissions help protect the public health by ensuring that newly introduced medical devices are safe and effective or substantially equivalent to other devices already legally marketed in this country, and that manufacturers of those medical devices have adequately notified the FDA of their activities and the devices manufactured.

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A review of our records does not show that you obtained marketing clearance before you began offering your products for sale, or that you registered and listed the company with FDA as a manufacturer. The kind of information you need to submit in order to obtain this clearance and register and list is described on FDA's medical device website at: <http://www.fda.gov/cdrh/devadvice>. Examples of the devices that lack premarket clearance include:

Surgical gowns:

The Mega Shield™ Gowns, Style 561 and 562;
The Fashion Shield® O.R. Gowns, Style 540, 541, and 542;
The Fashion Shield® O.R. Gowns, Style 547 and 548;
The Ultra Shield® O.R. Gowns, Style 531 and 534;
The Fashion Shield® D-Stat™ Gowns, Style 563;
The Liqua Shield II® O.R. Gowns, Style 553, 554, 555, 576, 577, and 578;
The O.R. Gowns, Style 508, 510, 557, 558, and 559;

Sterilization wraps:

The Fashion Blend Wrappers, Misty Style 1322 to 1326, Ciel Style 1332 to 1336, and Jade Style 1362 to 1366;
The Non-Slip Texture Shield® D-Stat™ Wrappers; and

Surgical drapes:

The Drape Sheets, Style 1395 to 1398.

Because you do not have marketing clearance or approval from the FDA, marketing your devices is a violation of the law. In legal terms, the devices are adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your devices are misbranded under the Act because you did not submit a section 510(k) premarket notification showing your devices are substantially equivalent to other devices that are legally marketed. Until you submit a section 510(k) premarket notification, and FDA reviews it and notifies you that you may market your devices, your products are also adulterated under the Act because the law requires, and you do not have an approved premarket approval application.

Since you have not submitted registration and listing documents with FDA identifying your company as a manufacturer, your devices are also misbranded under Section 502(o). Although your company is registered and listed as a specification developer, since the inspection revealed that devices are manufactured by your facility in Arkansas, you need to submit updated registration and listing identifying the facility as a manufacturer of medical devices.

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In addition, your devices are misbranded under Section 502(f)(1) of the Act because, although the devices are labeled as reusable, there is no labeling on or with the devices containing adequate directions for appropriate processing to ensure their safe reuse.

Our inspection determined that your devices are also 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 manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulations, as specified in Title 21, Code of Federal Regulation (CFR), Part 820. At the close of the inspection, our investigator issued to Mr. Richard T. Dawson, General Counsel and Secretary, a list of significant GMP inspectional observations [FDA-483 – copy enclosed] which include, but are not limited to, the following:

1. Failure of management with executive responsibility to ensure that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization [21 CFR 820.20]. For example:
 - a) Your firm has not established a quality policy [21 CFR 820.20(a)];
 - b) Your firm has not documented the appointment of a management representative [21 CFR 820.20(b)(3)]; and
 - c) Your firm has not established and maintained procedures for management reviews and quality audits [21 CFR 820.20(c)] and [21 CFR 820.22], respectively.
2. Failure to establish and maintain procedures for implementing corrective and preventive action that include the requirements listed in 21 CFR 820.100(a)(1) through (a)(7), and to document the required activities and their results, as required in 21 CFR 820.100(b).
3. Failure to establish and maintain complaint handling procedures for receiving, reviewing, and evaluating complaints by a formally designated unit [21 CFR 820.198] [FDA-483 Item 3]. For example, our inspection revealed that:
 - a) Your complaint handling procedures do not specify how complaints are investigated and handled by both the corporate site and manufacturing site;

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- b) The manufacturing site handled returned devices for alleged quality problems but did not have documentation available to support its or the corporate site's investigational findings;
 - c) The complaint handling procedure "Product Incident Report Form 3760," dated 1/93, does not include requirements that will ensure that complaints are processed in a uniform and timely manner and that complaints are evaluated for possible medical device reporting events;
 - d) According to your Vice President of Operations and Manufacturing Groups, who participated in the inspection, complaint files maintained by the corporate site were not tracked or trended; and
 - e) According to your Vice President of Operations and Manufacturing Groups, neither the manufacturing site nor the corporate site maintains a complaint log or complaint file number for each complaint.
4. Failure to establish and maintain procedures for finished device acceptance [21 CFR 820.80(d)] [FDA-483 Item 5]. For example, your firm has not established procedures for the inspectional activities performed following the sewing operations or for the authorization release of finished devices for distribution by a designated individual.
 5. Failure to establish and maintain the device master record to include or refer to the location of device specifications [21 CFR 820.181] [FDA-483 Item 7]. For example, your firm has not maintained product specifications for the cotton operating room (O.R) gowns, style numbers 508 and 510.
 6. Failure to establish and maintain procedures to control and approve all quality system documents [21 CFR 820.40][FDA-483 Item 6]. For example, your firm has not maintained change records for quality assurance procedures (i.e., In-Process Quality System Procedure, dated 10/16/01) and product specifications to include the document review and approval by designated individual(s), description of the changes, and effective date of the changes.
 7. Failure to establish and maintain medical device reporting (MDR) procedures [21 CFR 803.17] [FDA-483 Item 4].

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 the regulations. The specific violations noted in this letter and in the FDA-483

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issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems.

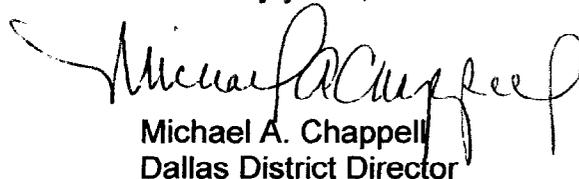
You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

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.

You should take prompt action to correct these violations. Failure to promptly correct these violations 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.

Please provide this office in writing within 15 working days of receipt of this letter a report of the specific steps you have taken, or will take to identify and correct 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 frame within which the corrections will be completed. Your reply should be directed to Thao Ta, Compliance Officer, at the above letterhead address.

Sincerely yours,



Michael A. Chappell
Dallas District Director

MAC:TXT:jab

Enclosure(s):

cc:

Mr. Ray Anderson, General Manager
Super Uniform Group, Inc.
Eudora Garment Division
304 Superior Drive
Eudora, Arkansas 71640