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November 22, 1999

Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863

WARNING LETTER  
CHI-2-00

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. David Smith, President  
Textus USA, Inc.  
1621 W. Chanute Road  
Peoria, Illinois 61615

Dear Mr. Smith:

An inspection of your registered medical device facility was conducted from May 6 to 19, 1999, by Investigator James Finn. The inspection revealed that the textile medical products distributed by your firm are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that the 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, manufacturing, packaging, storage, or installation are not in conformance with the Quality System Regulation (QSR) for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to ensure the integrity of the packaging of sterile medical device products. Our inspection found that there is no quantitative seal integrity testing performed after sterilization. The sampling plan for pre and post sterilization sterile package seal integrity has not been established and is not based on valid statistical rationale. The sterile package sealing process has not been validated. The sterile package design has not been validated. Our laboratory tested samples of your firm's products labeled, "Gauze Compress 1728 sq in Sterile," "Bandage Compress 4" Offset Sterile," and "Gauze Bandage 2 in x 6 yd Sterile" for package integrity. Our testing of "Bandage Compress 4" Offset" found one of ten failed (laboratory results are located in Attachment 1).
2. Failure to review certificates of irradiation, received from contract irradiators, for each irradiation run for completeness and/or assurance of acceptable sterilization parameters prior to release of products labeled and marketed as "Sterile".
3. Failure to audit your firm's contract manufacturer ( [REDACTED] ), [REDACTED] to assure they meet quality requirements.

4. Failure to include any requirement or process in your firm's complaint handling procedures to evaluate complaints to assure compliance with Medical Device Reporting (MDR) obligations.
5. Failure to record the following in Device History Records:
  - (a) Date of manufacture.
  - (b) Quantity manufactured.
  - (c) Quantity released for distribution.
  - (d) Lot acceptance prior to distribution.
  - (e) Label review.

The devices are misbranded under Section 502(b) of the Act in that the device labels do not include the name and place of business of the manufacturer, packer or distributor. Your firm does not maintain written agreements with all customers who further package your products into safety kits, as required by 21 CFR Section 801.150(a)(2); therefore, your products are not exempt from this regulation, as specified in 21 CFR Part 801.

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 Form 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment'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. No premarket submissions for devices, to which the Quality System Regulation deficiencies are reasonably related, will be cleared or approved until the violations have been corrected. No requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected and verified.

In order to facilitate FDA in making the determination that corrections of the deviations from the Quality System Regulation have been made, and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts for medical devices, and to resume marketing clearance for Class III devices for which a 510(k) has been submitted, and Certificates to Foreign Governments for medical devices manufactured at your facility located in Peoria, IL, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that he/she has conducted an audit of your establishment's manufacturing and quality assurance systems relative to the requirements of the device Quality System Regulation (21 CFR Part 820). You should also submit a copy of the consultant's report,

and certification by your establishment's CEO (if other than yourself) that he or she has reviewed the consultant's report and that your establishment, located in Peoria, IL, has initiated and completed all corrections called for in the report. The attached guidance, located in Attachment 2, may be helpful in selecting an appropriate consultant.

The initial certifications of audit and corrections, and subsequent certifications of updated audits and corrections, should be submitted to this office on the following dates:

- Initial certifications by consultant and establishment: June 1, 2000 (or sooner)
- Subsequent certifications of updated audits and corrections:
  1. June 1, 2001
  2. June 1, 2002

We acknowledge that Mr. Douglas Smith, Executive Vice President, responded by letter, dated May 20, 1999, to our Investigator's FDA-483. We do not consider his response adequate because it merely gives a completion date and does not explain how each inspectional observation will be corrected. We ask that your response to this letter provide the details and specifics to demonstrate that necessary corrections will be made. Also, please provide an update regarding the progress of your firm's corrective actions.

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

Please notify this office in writing within 30 working days of the receipt of this letter regarding the specific steps you have taken to correct the above violations. Also include an explanation of steps taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Michael A. Lang, Compliance Officer.

Sincerely,

\s\  
Raymond V. Mlecko  
District Director