



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Baltimore District Office  
6000 Metro Drive, Suite 101  
Baltimore, MD 21215-3215  
Telephone: (410) 773-5454

**WARNING LETTER**  
**04-BLT-20**

May 7, 2004

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Frederick J. Puente  
President  
Blind Industries and Services of Maryland  
2901 Strickland Street  
Baltimore, Maryland 21223

Dear Mr. Puente:

We are writing to you because on March 1-2, 2004, the Food and Drug Administration (FDA) conducted an inspection of your Cumberland, Maryland, facility which revealed a serious regulatory problem involving sterilization wraps, which are made and marketed by your firm.

Under a United States law, the Federal Food, Drug and Cosmetic Act (the Act), this product is considered to be a medical device because it is used to diagnose or treat a medical condition. The law requires, with certain exceptions, that manufacturers of medical devices obtain premarket approval or marketing clearance for their products from the FDA before they may offer them for sale. This helps 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.

Our records do not show that you obtained marketing clearance before you began offering your product for sale. The kind of information you need to submit in order to obtain this clearance is described on FDA's device web site at [www.fda.gov/cdrh/devadvice](http://www.fda.gov/cdrh/devadvice). FDA will evaluate this information and decide whether your product may be legally marketed.

Because you do not have marketing clearance from the FDA, marketing your product is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your product is misbranded under the Act because you did not submit a section 510(k) premarket notification that shows your device is 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 device, your product is also adulterated under the Act

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because the law requires, and you do not have, an approved premarket approval application that shows your device is safe and effective.

The above-stated inspection also revealed that your devices are adulterated under 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 Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure of management with executive responsibility to ensure that an adequate and effective quality system, as defined in 21 CFR 820.3(v), has been fully implemented and maintained at all levels of the organization, as required by 21 CFR 820.20. For example:
  - a. A management representative has not been appointed to ensure that quality system requirements are met, and to report to management on the performance of the quality system, as required by 21 CFR 820.20(b);
  - b. A quality plan has not been established, as required by 21 CFR 820.20(d); and
  - c. Quality system procedures have not been established, as required by 21 CFR 820.20(e).
2. Failure to establish and maintain procedures for implementing corrective and preventive actions (CAPA) and to document all activities, as required by 21 CFR 820.100.
3. Failure to establish procedures for acceptance activities including the acceptance of incoming product, the acceptance of in-process product, and the acceptance of finished devices, and to document such acceptance activities, as required by 21 CFR 820.80.
4. Failure to establish procedures to control labeling activities and failure to document the label used for each lot in the Device History Record, as required by 21 CFR 820.120.
5. Failure to establish procedures for identifying product throughout all stages of receipt, production, packaging, and distribution, as required by 21 CFR 820.60.

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 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.

In addition, 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

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prompt action to correct these violations. Failure to promptly correct these violations may result in the initiation of regulatory by the FDA without further notice. These actions include, but are not limited to, seizure of your product inventory, obtaining a court injunction against the further marketing of the product, or assessing civil money penalties.

We acknowledge your response dated March 4, 2004. The response is inadequate in that it does not contain sufficient information regarding the corrective actions you plan to take. 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 Steven B. Barber, Compliance Officer, 6000 Metro Drive, Suite 101, Baltimore, MD 21215.

Sincerely yours,

/s/

Roberta F. Wagner  
Acting District Director