



**DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION**

4298 Elysian Fields Avenue  
New Orleans, LA 70122-3896  
Telephone (504) 589-7166  
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HFI-35

10/28/97

October 17, 1997

**WARNING LETTER NO. 98-NOL-02**

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

Mr. Gene Minotto, President  
Basic American Medical Products, Inc.  
2935 Northeast Parkway  
Atlanta, Georgia 30360

Dear Mr. Minotto:

During an inspection of your firm, SSC Medical Products, located at 1691 S. Green St., Tupelo, Mississippi, on August 28 through September 4, 1997, our investigator determined that your firm manufactures AC-powered and manual adjustable hospital beds. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that your devices are misbranded within the meaning of Section 502(o) of the Act, in that the devices were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 and was not included in a list required by Section 510(j).

Additionally, these 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, packing, storage, or installation are not in conformance with Current Good Manufacturing Practice (CGMP) regulations for Medical Devices, as specified in 21 CFR, Part 820, as follows:

1. Failure to maintain copies of complaints, investigations, and/or decisions not to investigate complaints;
2. Failure to establish and maintain procedures to evaluate complaints to determine whether the complaint represents an event which is required to be reported to the Food and Drug Administration under 21 CFR, Part 803, Medical Device Reporting;
3. Failure to conduct planned and periodic audits of the quality assurance program in accordance with written procedures;
4. Device History Records fail to include results of component acceptance testing (i.e. dielectric tests) and any device identification or control number used;
5. Failure to establish procedures for document controls, purchasing controls, product identification, production and process controls, acceptance activities, the handling of non-conforming product, corrective and preventive actions, device labeling and distribution;
6. Failure to maintain records of employee training.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued 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.

Until these violations are corrected, Federal agencies will be 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. Additionally, no pending applications for premarket approval (PMA's) or export approval requests will be approved and no premarket notifications (Section 510(k)'s) will be found to be substantially equivalent for products manufactured at the facility in which the above CGMP violations were found until the violations have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Barbara D. Wright, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Ave., New Orleans, Louisiana 70122-3848. Should you have any questions concerning the contents of this letter, or if you should desire a meeting with the agency staff, you may contact Ms. Wright at (504) 589-7166.

Sincerely,



*acting*  
James E. Gamet  
District Director  
New Orleans District

Enclosures: FDA-483  
Device Registration & Listing Forms  
Device Registration & Listing Instruction Booklet

cc: Mr. F. Rowley Jackson, Vice President and General Manager  
Basic American Medical Products, Inc.  
2935 Northeast Parkway  
Atlanta, GA 30360

Mr. Jeffery L. Plunk, Operations Manager and Chief Engineer  
SSC Medical Products  
1691 S. Green St.  
Tupelo, MS 38801