



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
53907d

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

**WARNING LETTER**

March 12, 2003

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Kenneth R. Torrence  
President  
American Sunlight, Inc.  
7266-D Edinger Avenue  
Huntington Beach, CA 92647

W/L 26-03

Dear Mr. Torrance:

During an inspection of your firm located in Huntington Beach, California, from January 16 to 24, 2003, our investigator determined that your firm assembles mechanical and powered wheelchairs. These wheelchair products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection disclosed that 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, and storage are not in conformance with the Good Manufacturing Practice (GMP) requirements for the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish, maintain and control a quality system that is appropriate for specific devices manufactured [21 CFR 820.5 and 21 CFR 820.20]. For example,
  - Management with executive responsibility has not ensured that quality system requirements are effectively established and maintained.
  - Management with executive responsibility has not established a quality policy and objectives for, and commitment to quality for specific devices manufactured.
  - No quality plan defining the quality practices, resources, and activities relevant to devices that are designed and manufactured has been established or implemented.
  - No quality system procedures and instructions have been established and implemented.

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2. Failure to establish and implement procedures for conducting quality audits, and failure to conduct audits to verify that the quality system is effective in fulfilling the quality system objectives [21 CFR 820.22].
3. Failure to establish procedures for implementing corrective and preventive action addressing the analysis of sources of quality data to identify existing and potential causes of nonconforming product or other quality problems [21 CFR 820.100].
4. Failure to establish and implement procedures for receiving, reviewing, and evaluating complaints by a formally designated unit to ensure that all complaints are processed in a uniform and timely manner [21 CFR 820.198].
5. Failure to establish and implement procedures for document control and designate an individual(s) to review documents for adequacy and approval prior to issuance or when changes have been made to the documents [21 CFR 820.40]. For example, failure to prepare and approve a device master record (DMR) for each specific device manufactured which includes or refers to the location of device specifications, production specifications and methods, quality assurance procedures, and packaging and labeling procedures.

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 Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (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. Additionally, no pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Exportability 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 FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

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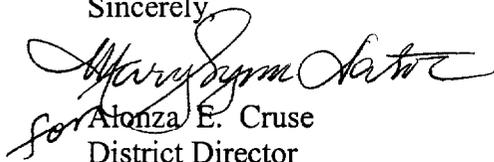
Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. 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.

If you have any questions relating to this letter please contact Senior Compliance Officer, Dannie E. Rowland at (949) 798-7649.

Please submit your response to:

Acting Director, Compliance Branch  
Food and Drug Administration  
19900 MacArthur Boulevard, Suite 300  
Irvine, CA 92612-2445

Sincerely,

  
Alonza E. Cruse  
District Director  
Los Angeles District Office

Cc: State Department of Public Health  
Environmental Health Services  
Attn: Chief, Food and Drug Branch  
601 North 7<sup>th</sup> Street, MS-35  
Sacramento, CA 94234-7320