



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region *m3588n*

Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

Telephone (973) 526-6006

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

April 3, 2000

**WARNING LETTER**

Mr. Michael Flowers  
President  
Electric Mobility Corp.  
One Mobility Plaza  
Sewell, NJ 08080

FILE NO: 00-NWJ- 28

Dear Mr. Flowers:

During an inspection of your firm located at One Mobility Plaza, Sewell, New Jersey, between January 14 and February 17, 2000, our investigator determined that your firm manufactures various configurations of scooters and power chairs that are used by handicapped individuals to enhance mobility. These scooters and power chairs are medical devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above stated inspection revealed that your scooters and power chairs 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 set forth in Title 21, Code of Federal Regulations (CFR) Part 820 as follows:

- 1. Your Management with executive responsibility failed to ensure that an adequate quality system has been established and maintained as required by 21 CFR 820.20. For example:**
  - a. A management representative was not appointed from September 1999 until January 21, 2000.
  - b. In-process quality control functions were not performed from January 13, 2000, through February 7, 2000, due to the absence and/or unavailability of the firm's only in-process quality inspector.
  - c. There were no written procedures for management reviews.
  - d. Although your firm conducted 20 internal audits from May 5, 1999, through October 8, 1999, your firm failed to implement any of the corrective action requests written as a result of these audits.

2. **Your firm failed to establish and maintain procedures for the design of your electric scooters and power chairs in order to ensure that specified design requirements are met, as required by 21 CFR 820.30(a).**
3. **Your design procedures for your Cavalier line of scooters (3 wheel, 4 wheel, and 4 wheel-short), which are contract manufactured by [REDACTED], do not contain the necessary elements of 21 CFR 820.30. For example:**
  - a. There were no procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements, as required by 21 CFR 820.30(d).
  - b. There were no procedures to ensure that formal documented design reviews of the design results are planned and conducted at appropriate stages of the device's design development, as required by 21 CFR 820.30(e).
  - c. There were no procedures for verifying the device design, as required by 21 CFR 820.30(f).
  - d. There were no procedures for validating the device design, as required by 21 CFR 820.30(g).
  - e. There were no procedures to ensure that the device design is correctly translated into production specifications, as required by 21 CFR 820.30(h).
  - f. There were no procedures for the identification, documentation, validation, or where appropriate, verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i).
4. **Your firm failed to establish a design history file for each type of device, as required by 21 CFR 820.30(j).**
5. **Your firm failed to establish and maintain procedures for verifying and validating the design for your Economy line of scooters, as required by 21 CFR 820.30(f).**
6. **Your firm failed to establish and maintain procedures for the identification, documentation, validation, or where appropriate, verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(j). Specifically, the investigator noted that changes to your [REDACTED] used in several of your power chairs, was not verified and/or validated.**

7. **Your firm's procedures for your Corrective and Preventive Action Subsystem (CAPA) failed to include an analysis of all sources of quality data to identify existing and potential causes of nonconforming product as required by 21 CFR 820.100(a)(1). Examples of quality data that should be included in your CAPA procedures include your Internal Failure Analysis Reports (IFAR), your Daily Rejection Summary Logs, and your Problem Logs.**
8. **Your firm's Supplier Corrective Action Report (SCAR) procedures do not include verifying or validating the corrective and/or preventive action to ensure that the action is effective and does not adversely affect the finished device as required by 21 CFR 820.100(a)(4). Three instances of inadequate documentation for the verification, and/or validation of changes made by your suppliers include SCAR #990302, #990401, and #990812.**
9. **Your procedures for Medical Device Reporting (MDR) did not include timeframe and baseline reporting requirements as required by 21 CFR 803.20(b)(3) and 803.55.**
10. **Your quality department failed to sign and review data and documents associated with your devices before final release. [21 CFR 820.80(d)]**
11. **Your in-process sampling plan for drive trains is not adequate in that it is not based on a statistical or validated method as required in 21 CFR 820.250.**
12. **Your firm failed to validate and/or verify the [REDACTED], installed in May 1999, and the use 9-inch ground wire instead of the specified [REDACTED] ground wire in the production of your controller assemblies. [21 CFR 820.70(b)]**
13. **Your firm did not validate your [REDACTED] computer system which is used for quality control data, order entry and inventory functions. [21 CFR 820.70(i)]**
14. **Your firm did not maintain your device history records in a manner to demonstrate that your devices were manufactured in accordance with their corresponding device master records. [21 CFR 820.184]**
15. **Your firm failed to have training procedures to ensure that all personnel are trained to adequately perform their assigned duties. [21 CFR 820.25(b)]**

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 483 issued to you may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the cause of the violations identified by the Food and Drug Administration (FDA). If the causes are determined to be system 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, requests for Certificates of Exportability and to Foreign Governments will not be cleared until the violations related to the subject devices have been corrected.

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

The agency is in receipt of your written response, dated February 29, 2000, to the FDA 483 issued to your firm on February 17, 2000. We acknowledge your firm's commitment to the Quality System Regulations; however, we have some comments to offer concerning your response. The procedures that you supplied were in "Preliminary Form." Have they been approved? Your response for #6 indicates that you feel [REDACTED] is responsible for design controls. As an initial importer and holder of the specifications for the electric scooter, your firm is responsible for design controls. The procedure you provided for design controls will be need to be more detailed when a project actually begins. Please refer to 21 CFR 820.30 for guidance on what needs to be included in a design control procedure.

During our review of your response, it was noted that specific observations were not mentioned as having been corrected. For example, we did not see a response concerning the three SCAR reports which were cited as not being verified and/or validated. Were these three reports corrected? Have the 20 Corrective and Preventative Action reports, which resulted as part of your firm's internal audits, been implemented yet?

Electric Mobility Corp. Warning Letter  
Sewell, NJ 08080  
April 3, 2000

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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 these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections 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 written reply should be directed to Diane B. Radice, Compliance Officer, FDA, 10 Waterview Blvd., Parsippany, NJ 07054.

Sincerely,

  
DOUGLAS I. ELLSWORTH  
DISTRICT DIRECTOR  
New Jersey District

DBR:slm