U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Electric Mobility Corp 4/14/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
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UPS OVERNIGHT DELIVERY

WARNING LETTER

Michael J. Flowers
President & Chief Executive Officer
Electric Mobility Corporation
599 Mantua Boulevard
One Mobility Plaza
Sewell, NJ 08080

11-NWJ-15

Dear Mr. Flowers:

During an inspection of your firm located in Sewell, New Jersey on October 19, 2010 through November 16, 2010, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures and distributes electric scooters and powered wheel chairs. Unde section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structur or function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. We received a response from Donna M. Huesken, Director of Quality and Regulatory, dated December 6, 2010, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations, that was issued to you. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures for validating the device design, as required by 21 CFR 820.30(g).

For example: Design validation procedures associated with the We Go 250 power chairs did not include provisions to ensure device specifications conform with the needs and intended uses of the characterized user population. Design verification activities were conducted to demonstrate design outputs (e.g. specifications) met input requirements; however, no design validation confirming the specifications met the needs of persons with disabilities or their caregivers was conducted. A patient transfer lock was added to the We Go 250 power chair design as a result of a post-design transfer user observation that the We Go 250 can rotate during patient transfer from the chair making transfer difficult.

We reviewed your response and conclude that it is not adequate because although you have provided an updated Design Control procedure and a signed change control document, no documentation demonstrating corrected design validation of the We Go 250 power chairs was provided.

2. Failure to establish and maintain adequate procedures for the identification, documentation, validation or where appropriate verification, review, an approval of design changes before their implementation as required by 21 CFR 820.30(i).

For example:

a. Your firm's Design Controls procedure (PSOP-6, Revision 17), in effect at the initiation of this inspection, does not address how changes to th design are to be handled when they are made after design inputs have been approved but before the design is transferred into production.

b. Your firm's Design Controls procedure (PSOP-6, Revision 17), in effect at the initiation of this inspection, states that the Engineering Change Notice (ECN) process is used to make changes to the design of existing products. The ECN procedures and forms (PSOP-7, W0401002, W0301001, EMCEN_27), in effect at the initiation of this inspection, do not ensure design changes are validated or where appropriate verified before their implementation.

Your firm changed the design of the We Go power chair by adding a passenger transfer lock. The ECN Evaluation Form (T10118) associated with this change indicates that no verification or validation testing was needed and no documented rationale for this decision was provided.

Your firm issued an ECN (R9180) on July 7, 2009, which changed the revision of the controller software used in the 300B and 700B model scooters from revision #8 to revision #9. This change increased the motor resistance from **(b)(4)**. There is no documentation to indicate that this change was validated/verified. According to your firm's engineer, the motor resistance affects the smoothness of the ride and scooter rollback.

We reviewed your response and conclude that it is not adequate because although you have provided updated Design Control procedures that include procedures for conducting appropriate design change, no evidence was provided to show that the concern documented in the observation was considered for application to other design changes that may not have been validated/verified.

3. Failure to review, evaluate, and investigate any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications as required by 21 CFR 820.198(c). This is a repeat deficiency from a previous inspection.

For example: