DEPARTMENT OF HEALTH AND HUMAN SERVICE

94992d
Public Health Service

Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

September 28, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
Ref. KAN 2004-19

Mr. Lee A. Penner, President
Penner Manufacturing, Inc.
102 Grand St., Suite A
Aurora, NE 68818-3200

Dear Mr. Penner:

During an inspection of your establishment located in Aurora, NE, April 22, 2004 through May 14, 2004 our investigator determined that your establishment manufactures patient lift systems. Patient lift systems are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that 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 the Quality System/Good Manufacturing Practice (QS/GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations regarding your design control system were noted as follows:

- The design history file was not established or maintained. [21 CFR 820.30(j)]
- Procedures to ensure that a device's design input requirements are appropriate and address its intended use, including user/patient needs, were not implemented. Design input requirements were not documented. [21 CFR 820.30(c)]
- Design outputs that are essential for the proper functioning of the device were not completely identified. [21 CFR 820.30(d)]
- Acceptance criteria were not established prior to the performance of verification activities. Design verification did not confirm that the design output meets the design input requirements. [21 CFR 820.30(f)]
- Procedures for validating the device design were not established, defined, and documented. [21 CFR 820.30(g)]

- An adequate design change control procedure was not established. [21 CFR 820.30(i)]

We have reviewed your firm's response dated May 27, 2004 to the FDA 483 issued at the close of the inspection on May 14, 2004. We acknowledge your efforts towards compliance with 21 CFR Part 820. Completing the required design control activities at this time for your medical device patient lifts currently on the market would be prudent and beneficial for your operations.

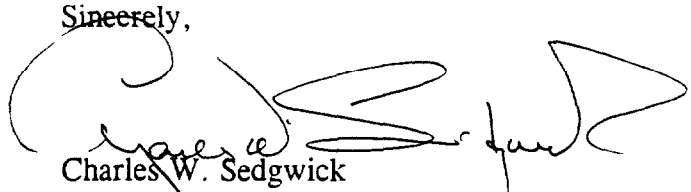
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

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 premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments 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 the Food and Drug Administration without further notice. These 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 status of the specific steps you have taken to correct the noted violations. Your reply should be sent to Nadine Nanko Johnson, Compliance Officer, at the above address.

Sincerely,



Charles W. Sedgwick
District Director
Kansas City District