



217690

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

## WARNING LETTER

### Via Federal Express

Our reference: 2939713

September 4, 2001

Richard L. Kaiser  
President and General Manager  
Chalgren Enterprises, Inc.  
380 Tomkins Court  
Gilroy, CA 95020

Dr. Mr. Kaiser:

We are writing to you because on August 7 – 9, 2001 FDA Investigator Christine Parmentier collected information that revealed serious regulatory problems involving electromyographic electrodes manufactured by your firm.

Under the Federal Food, Drug, and Cosmetic Act (Act), these products are considered to be medical devices, in that they are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers conform to the Quality System (QS) regulations for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), part 820. In addition, manufacturers are required to conform to the Medical Device Reporting (MDR) regulations in 21 CFR 803.

The inspection revealed that your devices are adulterated within the meaning of 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation are not in conformance with the QS regulation. These violations include but are not limited to:

### QS REGULATION/GMPs

1. Failure to establish and maintain procedures to ensure that the Device History Record for each lot is maintained to demonstrate that the device is manufactured in accordance with the Device Master Record and the Quality System regulation as required by 21 CFR 820.184. For example, Device History Record 277-930-48TP for Reusable Concave Dual Disc Bar Electrodes, lot # K169, does not include any manufacturing and quality records for [REDACTED] units that were assembled to replace rejected product in that lot.

2. Failure to establish and maintain procedures for changes to a process as required by 21 CFR 820.70(b). For example, you implemented the use of microscopes in the inspection of your product but you have failed to establish any procedures for this new inspection process.
3. Failure to verify or validate corrective and preventive actions to ensure that such actions are effective and do not adversely affect the finished device as required by 21 CFR 820.100(a)(4). For example, there is no verification or validation that the new inspection technique and/or vendor notification adequately corrected the problem of dull needles as described in Corrective Action Request # CAR-K001.
4. Failure to establish and maintain procedures for the evaluation of complaints to determine whether the complaint represents an event which is required to be reported to FDA under the Medical Device Reporting regulation as required by 21 CFR 820.198(a)(3).

#### **MEDICAL DEVICE REPORTING**

Your devices are also misbranded within the meaning of section 502(t)(2) in that there was a failure to furnish material or information required by or under section 519 of the Act. These violations include but are not limited to:

1. Failure to develop, maintain and implement Medical Device Reporting Procedures.

The specific violations noted in this letter and in the Inspectional Observations (Form FDA 483) issued to you at the conclusion 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 FDA. If the problems 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 awards of contracts. Additionally, no premarket submissions for a device to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export 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.

Letter to Richard L. Kaiser  
Chalgren Enterprises, Inc.

September 3, 2001  
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Please notify this office in writing within fifteen (15) working days of receipt of this letter, any steps you may have taken to correct the noted violation, including (1) the time frames within which the corrections will be completed if different from those in the annotated Form FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure similar violations will not recur.

Your response should be sent to Russell A. Campbell, Compliance Officer, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely,

  
Dennis K. Linsley  
District Director