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Food and Drug Administration  
Kansas City District  
Southwest Region  
11630 West 80<sup>th</sup> Street  
P.O. Box 15905  
Lenexa, Kansas 66285-5905  
Telephone: (913) 752-2100

April 12, 2000

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

**WARNING LETTER**

Ref. KAN 2000-012

Mr. Willard Lee Frickey  
President  
Raye's Inc.,  
204 W 2<sup>nd</sup> St.  
P.O. Box 320  
Ellis, KS 67637

Dear Mr. Frickey:

During our inspection of your establishment located in Ellis, Kansas, on March 14-16, 2000, our investigator determined that your establishment manufactures powered wheelchairs and electric adjustable patient beds. Powered wheelchairs and patient beds are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed 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 Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

Failure to conduct planned and periodic audits of the quality assurance program in accordance with written procedures [21 CFR 820.22]. Specifically, you have not conducted an audit of your quality assurance program for at least 2 years.

Failure to appoint a management representative to ensure the quality system requirements are established and maintained and that reports on the performance of the quality program are made to management with executive responsibility [21 CFR 820.20 (b) (3)].

Failure to establish and maintain procedures for implementing corrective and preventive actions to include analyzing processes, work operations, quality records, service reports, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems [21 CFR 820.100 (a)(1)].

bcc: -----

JWT:jwt

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 the FORM FDA-483 issued to you at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by 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.

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.

We have received and reviewed your letter, dated March 24, 2000 in response to our inspectional findings. In general, we find it inadequate. Your response lacks supporting evidence and in some instances, fails to address underlying issues that may have contributed to or resulted in the deficiencies.

For example, in your response to Observation #1, you did not identify the management representative nor did you address how this person is to carry out the duties and responsibilities required by the regulation.

In your response to Observation #2, you stated that you are formally documenting and implementing a corrective and preventive action (CAPA) procedure/program. Please provide a copy of the procedure(s) you have written and approved to implement the CAPA program and identify how you plan to monitor and evaluate adherence to the new procedure(s).

You responded that quality audits would be done in accordance to a schedule that was put into place on 3/24/00. Please provide a copy of this schedule and identify when the audit of the Quality Assurance Program will be done. If the audit has been completed, please provide the date(s) of the audit.

In your response to Observations 6 and 7 you stated the complaint procedure would be revised. Please provide a copy of the revised procedure(s). We have concerns about the adequacy of an end of the month review of all complaints; in that those complaints involving injury, illness or device failure may not get evaluated and or investigated in a timely manner. Further, please explain how you plan to monitor and evaluate adherence to the new procedure(s).

In your response to Observation #9, you stated that you revised the standard operating procedure: "QC 1022, Final Inspection Rehab. Platforms". Please provide a copy of the revised procedure and explain how you plan to monitor and evaluate adherence to this newly revised procedure.

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 and to address our concerns. Please include 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.

Please direct your response to Mr. John W. Thorsky, Director of Compliance at the address listed above.

Sincerely yours,



Mary Woleske  
Acting District Director  
Kansas City District