



Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000
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November 18, 1996

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. David O. Weaver, President
D.O. Weaver and Company
565-C Nucla Way
Aurora, Colorado 80011

PURGED

Ref. # - DEN-97-04

Dear Mr. Weaver:

During an inspection of D.O. Weaver and Company conducted between October 15 and 21, 1996, Engineer Thai Duong determined that your firm manufactures various EEG/ECG skin prepping and conductive paste products. These products 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 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 the manufacturing, packing, storage, or installation are not in conformance with Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820) as follows:

1. Failure to conduct all processing control operations in a manner designed to assure that the device conforms to applicable specifications, as required by 21 CFR 820.100(b)(2). For example, your firm has failed to validate any of the manufacturing processes used to produce Omniprep, Nuprep, and Ten20 Conductive. There is no evidence to demonstrate that the mixing process will assure that the finished products are mixed homogeneously.
2. Failure of the quality assurance program to assure that approval or rejection of all finished devices is performed, as required by 21 CFR 820.20(a)(2). For example, the quality assurance program did not reject three lots of Omniprep produced using more than the approved specification listed in the Device Master Record, nor

lots of Omniprep produced using less than the amount specified in the Device Master Record.

3. Failure to establish adequate procedures for specification control measures to assure the design basis for the device and components is correctly translated into approved specifications, as required by 21 CFR 820.100(a)(1). For example, your firm does not have adequate procedures to show that a two year expiration date for Omniprep, and a three year expiration date for Nuprep and Ten20 products are appropriate.
4. Failure to base sampling plans for testing and release of finished devices on an acceptable statistical rationale, as required by 21 CFR 820.160. For example, the sampling plan used for bioscreen in finished device inspection requires one container to be collected and analyzed per production lot. This sample size is not based on an acceptable statistical rationale.
5. Failure to record and maintain information relative to identity, effectiveness and device performance from complaints received, as required by 21 CFR 820.198(a). For example, at least complaints regarding Omniprep failed to record the lot number of the subject device or the nature of the complaint. This is also true for a complaint regarding the Ten20 product. Also, your firm is failing to follow the " " procedure in that complaints were observed as not being documented on the "Complaint Review Form."
6. Failure to investigate failures of devices released for distribution, as required by 21 CFR 820.162. For example, several complaints received regarding the consistency of Omniprep and Ten20 products were not investigated, no conclusions were reached regarding the cause of the reported failure, and no follow up to correct the problem was made.
7. Failure to maintain a device history record to demonstrate that the device is manufactured in accordance with the device master record, as required by 21 CFR 820.184. For example, complaints were received for Omniprep with incident dates of 11/94 and 8/95. There was no device history record maintained for this lot.
8. Failure to develop, implement and maintain any written procedures for handling MDR reportable events, as required by 21 CFR 803.17.

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 at the closeout 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 the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

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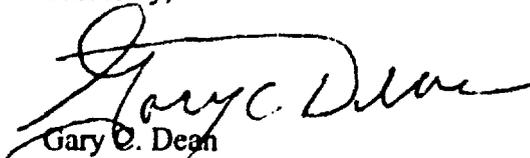
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Federal agencies are advised of the issuance of all Warning Letters regarding medical devices so they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP 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.

Please notify this office within 15 days of receipt of this letter, of the specific steps you will be taking to comply with our request.

Your reply should be sent to the Food and Drug Administration, Denver District Office, Attention: David K. Glasgow, Acting Compliance Officer, at the above address.

Sincerely,



Gary C. Dean
District Director

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Mr. David O. Weaver

bcc:

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