



Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

April 21, 1998

WARNING LETTER

Richard G. Wood, President
Eudaemonic Corporation
7031 North 16th Street
Omaha, NE 68112

Ref.# - 98-KAN-014

Dear Mr. Wood:

During an inspection of your firm located in Omaha, Nebraska, on February 17 through March 19, 1998, our investigator determined that your firm manufactures a powder and gel wound dressing. These wound dressings are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (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 current good manufacturing practice (CGMP) requirement of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, to include, but not limited to, the following:

1. Failure to have written procedures for Medical Device Reporting (MDR) incidents [21 CFR 803.17].
2. Failure to have an MDR Event File [21 CFR 803.18].
3. Failure to establish written procedures for a Quality Audit program, and to perform such audits of your Quality System [21 CFR 820.20(b)]. This would also be a violation of the Quality System Regulation, 21 CFR 820.22.
4. Failure to maintain a complete and accurate Device Master Record for "██████████" in that it does not include complete device specifications; component specifications; production process specifications; production methods and

procedures; and device acceptance criteria [21 CFR 820.181]. This would also be a violation of the Quality System Regulation, 21 CFR 820.181.

5. Failure to maintain complete Device History Records for "Multidex Gel" in that it does not include copies of the labeling [21 CFR 820.184]. This would also be a violation of the Quality System Regulation, 21 CFR 820.184.
6. Failure to implement a change procedure program for any changes in device specifications, process, and/or procedures provided to you by the specifications developer [21 CFR 820.100]. This would also be a violation of the Quality System Regulation, 21 CFR 820.30(h) & (i); 21 CFR 820.70(a) & (b); and 21 CFR 820.75.
7. Failure to implement an adequate environmental and contamination control program which addresses employee training concerning equipment cleaning; environmental monitoring; cross contamination from using multi-purpose equipment; and the air filtration system [21 CFR 820.46]. This would also be a violation of the Quality System Regulation, 21 CFR 820.70(c).

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.

We acknowledge that you have submitted to this office a response dated March 27, 1998, concerning our investigator's observations noted on the Form FDA 483. We are reviewing your response and will provide you our comments under a separate letter.

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 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.

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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 FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including 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. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,



W. Michael Rogers
District Director
Kansas City District

CC: [REDACTED]