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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration  
Denver District Office  
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Denver, Colorado 80225-0087  
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September 27, 2002

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. David J. McNally  
President & CEO  
Zevex, Inc.  
4314 Zevex Park Ln.  
Salt Lake City, Utah 84123

Ref. #: DEN-02-16

Dear Mr. McNally:

On July 29-31, 2002 Investigator Nicholas R. Nance of our office conducted an inspection of Zevex, Inc., Salt Lake City, UT. Our investigator determined that your firm manufactures various products, including enteral feeding pumps. These products 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 (21 CFR), Part 820. The deviations are as follows:

1. Failure to identify sources of quality data and statistical methods to be used, to identify existing and potential causes of nonconforming product, or other quality problems as required by 21 CFR 820.100 (a) (1). Specifically, your CAPA procedures do not list or identify the quality data sources available or the statistical methods to be used to analyze these data sources.
2. Failure to establish adequate CAPA procedures in that corrective and preventative actions are not verified or validated to ensure that such actions are effective and do not adversely affect

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the finished device, as required by 21 CFR 820.100(a)(4). Specifically, neither CAPA/CAR procedures nor the CAR form address verification or validation.

3. Failure to investigate the cause of nonconformities related to product, processes, and the quality system as required by 21 CFR 820.100(a)(2). Specifically, your CAPA/CAR procedures do not require a determination of the cause of nonconformities.
4. Failure to establish adequate procedures or document rework to ensure the product meets its current approved specifications as required by 21 CFR 820.90 (b) (2). Specifically, review of device history records for Enteralite pumps revealed incidents of pumps failing testing with no record of retesting as required by procedures.
5. Failure to maintain adequate complaint procedures to ensure all complaints are processed in a uniform and timely manner as required by 21 CFR 820.198(a). Specifically, review of complaint data revealed lack of complaint forms required by your own complaint procedures and the lack of a system to identify, track, and investigate complaints.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your establishment is in compliance with all requirements of the Federal 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.

We acknowledge receipt of your August 9, 2002 response to the FDA-483. We are unable to evaluate the effectiveness of your response, as no supporting documents were included.

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 QS/GMP deficiencies are reasonably related will be cleared until the violations are 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.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of any other additional steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

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Your response should be sent to H. Tom Warwick, Compliance Officer, Food and Drug Administration, Denver District, P. O. Box 25087, Denver, CO 80225-0087. If you have any further questions, please feel free to contact Mr. Warwick at (303) 236-3054.

Sincerely,



B. Belinda Collins  
District Director

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