



April 1, 2002

VIA FEDERAL EXPRESS

Our ref: 2950583

Daniel Fisher, President
Biozone Laboratories
580 Garcia Avenue
Pittsburg, CA 94565

WARNING LETTER

Dear Mr. Fisher:

During an inspection of your establishment on February 11 through 20, 2002, Investigator Marshalette O. Edwards of this office found significant violations of the Federal Food, Drug, and Cosmetic Act (Act) as they pertain to products manufactured in your plant, which are drugs within the meaning of Section 201(g) of the Act.

Drug products manufactured by your firm are adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the methods used in, or the facilities or controls used for their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice, as set forth in Title 21, Code of Federal Regulations, Parts 210 and 211, as follows:

Failure to establish a stability testing program to assess the stability characteristics of drug products, as required by 21 CFR 211.166. No stability studies have been conducted on any of the drug products manufactured by your firm.

This identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the good manufacturing practice regulations. Federal agencies are advised of the issuance of all warning letters concerning drugs so that they may take this information into account when considering the award of contracts.

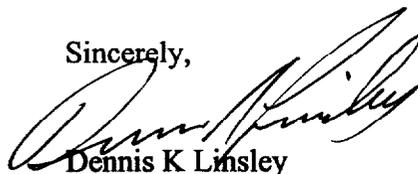
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

We have reviewed your February 28, 2002, written response to our inspectional findings. With the exception of the stability issue, your responses appear to address the violations.

Within (15) working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within (15) working days, state the reason for the delay and the time within which corrections will be completed. Please include any documentation necessary to show that compliance has been achieved.

Your reply should be directed to Suzanne Schenck, Compliance Officer.

Sincerely,



Dennis K Linsley
District Director

cc:

Brian C. Keller, Executive Vice President