



DEPARTMENT OF HEALTH & HUMAN SERVICES

1/28/98
LB 1/23/98 D1065B

Certified/Return Receipt Requested

January 23, 1998

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

Telephone: (913) 752-2100

WARNING LETTER

Mary Barnes, President
Vita-Erb, Ltd.
1358 North Stewart Avenue
Springfield, MO 65802

Ref. # - KAN-98-006

Dear Ms. Barnes:

During an inspection of your manufacturing facility located in Springfield, Missouri, conducted on December 11 and 12, 1997, our investigator documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211) which cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Observations include, but are not limited to the following: 1) failure to keep foreign material from entering empty bottles used for medicated shampoo; 2) failure to assure hair restraints are used by employees in the production and filling areas; 3) failure of the medicated shampoo batch records to list correct ingredient weights; 4) failure of production records to list all required steps such as mixing times, and raw material tests and calculations.

The above identification of violations 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. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. Additionally, export approval requests may not be approved until the above violations are corrected.

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Vita-Erb, LTD.

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

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps that are being taken to correct the noted violations and to prevent their recurrence. 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

Orig.: Addressee
bcc: LF; FF(1929644); HFA-224; HFD-300; HFI-35/DIB(via FOI); HFC-210; HFC-240(MPQAS); SP/RP; WMR(chrono); GDD; RF

CRP:tlw