



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

g3305d

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

Telephone: (913) 752-2100

June 7, 2002

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN 2002-007

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

Dear Ms. Barnes:

An inspection of your over-the-counter pharmaceutical, device, and cosmetic manufacturing facility located in Springfield, Missouri, was conducted April 29 through May 2, 2002, by an investigator representing the Food & Drug Administration (FDA). During this inspection, deviations from Title 21, Code of Federal Regulations, Part 211 [21 CFR 211] Current Good Manufacturing Practice (CGMP) Regulations for Finished Pharmaceuticals were documented. These deviations cause your over-the-counter pharmaceutical products to be adulterated under Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Deviations noted include, but are not limited to, the following:

- Failure to test each lot of over-the-counter (OTC) pharmaceutical finished product for identity and strength of each active ingredient prior to release. [21 CFR 211.165(a)]
- Failure of the quality control unit to review OTC drug product production and control records to determine compliance with all established, approved written procedures before a batch is released or distributed. [21 CFR 211.192]
- Failure to maintain complete production records as follows:

Master production and control records lack a statement of theoretical yield including the maximum and minimum percentages of theoretical yield beyond which investigation is required. [21 CFR 211.186(b)(7)]

Actual yield and percentages of theoretical yield are not determined at the conclusion of each appropriate phase of manufacturing of the drug product. [21 CFR 211.103]

Batch production and control records do not include the identification of the persons performing and checking each significant step in the operation, for each batch of drug product produced. [21 CFR 211.188(b)(11)]

Batch production and control records do not include the specific identification of each batch of component used for each batch of drug product produced. [21 CFR 211.188(b)(3)]

- Failure to perform at least one specific identity test on each incoming lot of OTC drug product component. [21 CFR 211.84(d)(2)] Specifically, your firm relies on a Certificate of Analysis from the raw material supplier(s) without performing at least one quantifiable test to verify the accuracy of the supplier(s) Certificate of Analysis. No vendor validation has been performed.
- Failure to keep records for the maintenance, cleaning, sanitizing, and inspection of equipment used in pharmaceutical production. [21 CFR 211.67(c)]

The Obedience Medicated Shampoo C-S-S is misbranded under Section 502(c) of the Act. The product label does not contain complete product warnings in accordance with 21 CFR 358.750(c)(2).

The PES 828 Pain Relieving Gel is misbranded under Section 502(a) of the Act. The product label does not declare the actual concentration of active ingredient menthol that the product is formulated to contain.

In addition, we stress to you that anti-microbial hand cleaners are defined as drugs per Section 201(g) of the Act. Thus, FDA's Current Good Manufacturing Practice regulations for finished pharmaceuticals [21 CFR 211] pertain to the manufacturing of such products.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your firm adheres to all current regulations applicable to your operations.

By copy of this letter, we are advising the General Services Administration (GSA) and Department of Veterans Affairs (VA) that our inspection of your firm revealed significant deviations from the Act so they may consider this information when awarding government contracts.

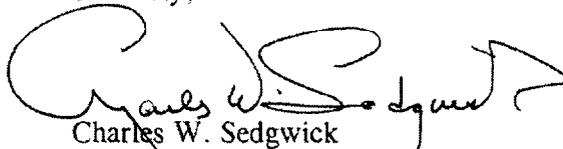
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You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your OTC drugs.

It is necessary for you to take action on this matter now. Please notify this office in writing within fifteen (15) working days from the date you received this letter. Your response should specifically identify the actions you are taking to correct the violations and provide specific timeframes for achieving compliance.

Your reply should be sent to Nadine Nanko Johnson, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick". The signature is stylized and written over the printed name below it.

Charles W. Sedgwick
District Director
Kansas City District

cc: Dept. of Veterans Affairs
Attn: Maria Alba
5th & Roosevelt Rd.
P.O. Box 5000
Hines, IL 60141

General Services Administration
7FXPM-J8, Room 6A24
Attn: Carolyn Girard
819 Taylor St.
Fort Worth, TX 76102