



September 26, 2003

Chicago District  
550 West Jackson Blvd., 15th Floor  
Chicago, Illinois 60661  
Telephone: 312-353-5863**WARNING LETTER**  
**CHI-20-03****CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Dirk Hejnal, President  
Westfalia-Surge, Inc.  
1354 Enterprise Dr.  
Romeoville, IL 60446-1069

Dear Mr. Hejnal:

An inspection of your veterinary drug manufacturing facility at Romeoville, Illinois, conducted on April 1, 2, and July 8, 2003, by the U. S. Food and Drug Administration (FDA) found significant deviations from the Current Good Manufacturing Practice for Finished Pharmaceuticals (CGMP) regulations, Title 21, *Code of Federal Regulations*, Part 211 (21 CFR 211). These deviations cause the veterinary drugs manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). In addition, the inspection revealed that your firm is marketing **VICTORY TOPICAL SOLUTION** in violation of the Act. The CGMP deviations were presented to your firm on form FDA-483, Inspectional Observations, at the close of the inspection on April 2, 2003. The significant observations were as follows:

- The batch production and control records failed to document the accomplishment of significant steps in manufacturing. For example, an additional amount of the active ingredient iodine was added to two lots of teat dip to bring them up to specifications, but the batch records failed to document calculations and steps in adding the ingredient.
- The batch production and control records failed to include complete information relating to the production and control of each batch. For example, entries were made on a batch record for Theratec on 4/1/03, before those operations were performed.
- The written procedures for handling complaints did not match the procedures actually used. For example, the written procedures do not address the computerized database system that is currently used to enter the complaint and record follow-up actions.
- The written records of investigation of drug complaints did not include the findings of the investigation and the follow-up in all cases.
- Unexplained discrepancies were not thoroughly investigated, as occurred when a Theratec label was found on a drum containing "DermaSept" (a non-drug product).

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- Laboratory records failed to include complete data derived from all tests, examinations, and assays necessary to assure compliance with established specifications and standards.
- Laboratory records failed to include the initials or signature of a second person showing the original records have been reviewed for accuracy, completeness, and compliance with established standards.

The label for **VICTORY TOPICAL SOLUTION** states that it is proven effective for control of hairy foot warts (Digital Dermatitis). Because the product is intended for use in the cure, mitigation, treatment or prevention of a disease, it is a drug under Section 201(g) of the Act. It is regarded as a "new animal drug" under Section 201(v) of the Act since it is not generally recognized as safe and effective for its intended use by scientific experts. As a new animal drug, this product is unsafe within the meaning of Section 512 of the Act since it is not the subject of a New Animal Drug Application (NADA), and it is therefore adulterated within the meaning of Section 501(a)(5) of the Act. We also note that the use of this product could result in residues in milk and/or meat that may pose a food safety risk for humans.

The above is not intended to be an all-inclusive list of violations. As a manufacturer of veterinary drugs, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of the receipt of this letter of the steps you have taken to correct the noted violation. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date that the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Please send your reply to the Food and Drug Administration, Attention: Paul A. Boehmer, Compliance Officer, at the above address. If you have questions regarding any issue in this letter please contact Mr. Boehmer at (312) 596-4217.

Sincerely,

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Arlyn H. Baumgarten  
District Director

Enclosure: FDA Form 483