



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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# PURGED

Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

August 5, 1999

## WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 39

Gary M. Steuart  
Owner  
Steuart Laboratories  
237 Second Avenue NW  
Harmony, Minnesota 55939

Dear Mr. Steuart:

During our inspection of your facility, a human and veterinary drug manufacturing operation, located in Harmony, Minnesota, our investigator found serious violations of the Current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Steuart's Healing Cream is a drug within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). Miracle Heel, Uterine Cleanse, Chlorhexidine Solution and Udder Heal are animal drugs within the meaning of Section 201(g)(1)(C) of the Act as they are intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in animals. Steuart's Healing Cream, Miracle Heel, Uterine Cleanse, Chlorhexidine Solution and Udder Heal are adulterated within the meaning of Section 501(a)(2)(B) of the Act.

The violations observed during our inspection include but are not limited to the following:

1. Failure to have written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess (21 CFR 211.100).

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2. Failure to withhold from use each lot of components, containers, and closures from use until the lot has been sampled, tested or examined [21 CFR 211.84(a)].
3. Failure to determine actual yields and percentages of theoretical yields at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product (21 CFR 211.103).
4. Failure to have appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient prior to release (21 CFR 211.165) in that there is no finished product testing.
5. Failure to prepare master production and control records for each drug product (21 CFR 211.186) in that master records are missing or incomplete.
6. Failure to prepare production and control records for each batch of drug product produced and to include complete information relating to the production and control of each batch (21 CFR 211.188) in that batch records are incomplete.

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts. As a manufacturer of veterinary drugs you are responsible for ensuring your overall operation and the products you manufacture and distribute are in compliance with the law.

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. This is official notification that FDA expects all your locations to be in compliance.

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In addition, FDA does not consider your Steuart's Healing Cream to be a homeopathic product. Drug products containing homeopathic ingredients in combination with non-homeopathic active ingredients are not considered by policy to be homeopathic drug products. Homeopathic drug products should be labeled as homeopathic and listed in the Homeopathic Pharmacopeia of the United States (HPUS), an addendum to it or its supplements. The potencies of homeopathic drugs are specified on the label in terms of dilution.

Also, during the same inspection on June 22 and July 8, 1999, our investigator found the following products are still manufactured and distributed by your firm: **Uterine Cleanse** and **Miracle Heel Veterinary Ointment**. There has been no change in the various claims these products make and, therefore, the products are still considered to be unapproved animal drugs as noted in our March 19, 1999, Warning Letter. New animal drugs may not be marketed without FDA approval.

The label for **Uterine Cleanse** states that the product is useful in treating the normal postpartum uterus and implies that the product may be used in the treatment of calvings complicated by dystocia or a retained placenta that could be followed by a severe bacterial infection of the uterus. It bears the claim: "Infuse 30cc as an aid in flushing the essentially normal postpartum uterus. Repeat treatments if exams determine that the uterus needs additional flushing." The presence of allantoin does not render this product a drug. Rather it is the intended use of this product. This product is considered to be a drug within the meaning of Section 201(g)(1)(C) of the Act because it is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in an animal.

The label for **Miracle Heel**, a veterinary ointment, states "An ointment containing allantoin, which soothes and promotes the healing of wounds. "Suggested uses: Wounds and dry or cracked hooves."

These products are "new animal drugs" as defined by Section 201(v) because they are not generally recognized among experts as safe and effective for their labeled uses. These drugs are adulterated within the meaning of Section 501(a)(5) of the Act because they are unsafe within the meaning of Section 512 of the Act. Section 512 of the Act deems in part a new animal drug to be unsafe unless an approved New Drug Application (NADA) is in effect demonstrating the safety and effectiveness of the product.

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We request that you reply within 15 days of your receipt of this letter stating the action you will take to discontinue the marketing of these drugs or otherwise bring them into compliance. 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 Compliance Officer Carrie A. Hoffman at the address on the letterhead.

Since you have failed to make corrections to violations cited in our previous Warning Letter, we believe it is now prudent to have you meet with us in our Minneapolis Office. We have scheduled a meeting for Tuesday, August 31, 1999, at 1:00 p.m. Please bring copies of documentation demonstrating that corrections have been made. If the meeting arrangements conflict with your schedule please contact Ms. Hoffman at (612) 334-4100 ext. 159 to make other arrangements.

Sincerely,



James A. Rahto  
Director  
Minneapolis District

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