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

March 19, 1999

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 22

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

Dear Mr. Steuart:

During a recent inspection of your facility conducted by the Food and Drug Administration we found the following products are manufactured and distributed by your firm: **Uterine Cleanse**, **Miracle Heel Veterinary Ointment**, and **Chlorhexidine Scrub**. These products make various claims which make them animal drugs.

- * 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."

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- * 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."
- * The **Chlorhexidine Scrub** label states "FOR ANIMAL USE ONLY" and "Chlorhexidine Scrub...exhibits bactericidal activity against a wide range of micro-organisms. Wet hands...Lather thoroughly. Rinse...water."

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 Animal Drug Application (NADA) is in effect demonstrating the safety and effectiveness of the product.

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

If the following changes are made to the labeling of **Miracle Heel Veterinary Ointment** and **Chlorhexidine Scrub** we would not object to the marketing of these products at this time:

Miracle Heel Ointment:

- * Delete the term "Miracle" since the product's effectiveness is unknown.
- * Revise the statement "Soothes and promotes the healing of wounds" to "can be used in the treatment of superficial cuts and scratches."
- * Clarify the directions on how to cleanse the wound. A statement consistent with "wash affected area with soap and water, then apply ointment to affected area" would suffice.
- * List the amount, kind, and percent alcohol on the product label.
- * Declare the percentage of the active ingredient in the product, i.e. allantoin.
- * Declare the intended animal species. We do not consider the vignette of a horse's hoof, by itself, to be adequate for this purpose.

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Chlorhexidine Scrub – The directions for use for this product must be clarified and caution statement consistent with the directions for use added:

- * The product is labeled “FOR ANIMAL USE ONLY” but the directions for use suggest that the product is actually for hand washing. With directions for hand washing this product is subject to additional regulations as a human drug.
- * If intended as a pre-surgical scrub for animals the claims should be limited to the following: (1) Antiseptic; (2) Animal patient skin preparations and/or (3) For preparation of skin before surgery.
- * If intended for use as an animal skin cleanser containing low concentrations of chlorhexidine (about 2%) claims must be limited to antiseptic, antiseborrheic, or similar claims. We object to antibacterial and antifungal claims.
- * Delete directions for human use from the label.
- * Add the warning statement “**CONTRAINDICATIONS: DO NOT USE PRODUCT ON CATS OR KITTENS**” to the label. This statement should be isolated from other statements on the label and should be boxed or otherwise prominently displayed.
- * Add the cautionary statement “**NOT FOR OTIC USE.**”
- * Delete the statement “Chlorhexidine Scrub is a mild scrub containing Chlorhexidine Gluconate 2% that exhibits bactericidal activity against a wide range of micro-organisms.”
- * Since you intend this product solely for use on animals revise the First Aid section to address reactions in animals.
- * Add the following statements to the WARNING statement:
 - (A) For external use only
 - (B) Do not use in the eyes

Our not objecting to the marketing of Miracle Heel Ointment and Chlorhexidine Scrub if the labeling is revised does not constitute an approval or affirmation of their safety and effectiveness for these uses. If circumstances change in the future, FDA may change its regulatory position.

The above is not intended to be an all-inclusive list of violations. FDA's Center for Veterinary Medicine is currently reviewing the product  which is manufactured by your firm. Additional violations related to this product may be identified. As a manufacturer of veterinary drugs you are responsible for assuring

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your overall operation and the products you manufacture and distribute are in compliance with the law.

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.

Sincerely,



James I. Roberts
Acting Director
Minneapolis District

CAH/ccl