



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
933201

May 23, 2002

Dallas District  
4040 North Central Expressway  
Dallas, Texas 75204-3145

Ref: 2002-DAL-WL-17

**WARNING LETTER**

**VIA CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. John McCready,  
Chief Executive Officer  
Cut Heal Animal Care Products, Inc.  
923 South Cedar Hill Road  
Cedar Hill, Texas 75104

Dear Mr. McCready:

This letter concerns animal drug products manufactured and marketed by your firm under the label of Cut-Heal Animal Care Products, Inc. An investigator of the Food and Drug Administration (FDA) conducted an inspection of your firm at the above referenced address on January 2 and 22, 2002. Based on the manufacturing processes, labels, and promotional materials obtained during that inspection, the marketing of these products violates the Federal Food, Drug, and Cosmetic Act (the Act) as described below.

CUT-HEAL® Multi+Care™ Liquid Wound Care  
CUT-HEAL® Multi+Care™ Aerosol Wound Spray  
CUT-HEAL® Multi+Care™ Wound Powder  
CUT-HEAL® Multi+Care™ Ointment Wound Care  
CUT-HEAL® HOOF HEAL™  
CUT-HEAL® PAD HEAL™  
CUT-HEAL® derma.calm™ For Horses  
CUT-HEAL® Multi+Care™ Wound & Hot Spot Spray for Dogs  
CUT-HEAL® derma.calm For Dogs

The representations on the labeling for these products indicate that the products are intended for use in the prevention of disease in animals and that they are intended to affect the structure or function of animals. The products are therefore drugs under section 201(g)(1)(B) and (C) of the Act. The products are also "new animal drugs" under section 201(v) of the Act because FDA is not aware of any scientific evidence showing the products are safe and effective.

Because none of the products listed above are covered by an approved New Animal Drug Application (NADA), as required by section 512(a)(1)(A) of the Act,

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Cut Heal Animal Care Products, Inc.  
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the products are adulterated pursuant to section 501(a)(5) of the Act, and are being illegally marketed.

The violations described above are not meant to be all-inclusive. It is your responsibility to ensure that all drug products manufactured and distributed by your firm comply with the Act.

In FDA's files on your firm, is a copy of a letter addressed to you by this office on January 16, 1992, advising of the unapproved new animal drug status of your animal drug products, based on a review of the products by FDA's Center for Veterinary Medicine. The labeling of these products today bear identical or similar treatment claims, including "heals from the inside out", and "preventing Proud Flesh". Many of your products are for horses and hooved animals.

Some although not all of your animal drugs are labeled to indicate the products should not be used in food producing animals. It is your responsibility to assure that your animal drug products do not create potential health concerns for humans, as well as for certain animal species, based on ingredient composition, combinations, and/or indications for use of the products.

We request that you take action immediately to correct these violations. Failure to do so may result in regulatory action without further notice. This action may include seizure and/or injunction.

Please respond to this office in writing within fifteen (15) working days of receipt of this letter. Your response should describe the specific actions you will take, or have taken, to correct the violations. It should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed. Please send your reply to James R. Lahar, Compliance Officer, at the above address.

Sincerely,



Michael A. Chappell  
Dallas District Director

bcc: MAC/jrl