



Food and Drug Administration  
Rockville MD 20857

July 2, 1998

REGISTERED MAIL

• NADA 141-082

Judith E. Spiegel, Ph.D.  
Director, Regulatory Affairs  
Heska  
1825 Sharp Point Drive  
Fort Collins, CO 80525

Dear Dr. Spiegel:

We refer to your Drug Experience Report dated May 29, 1998 for Heska™ Periodontal Disease Therapeutic (doxycycline hyclate), NADA 141-082.

Specifically, we refer to the following pieces of promotional labeling submitted in this report: 1) Technical Bulletin: Periodontal Disease: Diagnosis, Treatment, and Control; 2) Product literature: Introducing the HESKA™ Periodontal Disease Therapeutic; and 3) the educational video tape. These promotional labels explicitly state that tetracyclines have other additional benefits such as anti-collagenase activity and anti-inflammatory properties.

We deem these statements to be new claims which are not provided for in the approved application and are not in compliance with 21 CFR §§514.1(b)(11) and 202.1(e)(6)(i). As such, the promotional labeling making these unapproved claims causes your product to be misbranded under §502(a) and adulterated under 501(a)(5) of the Act.

We request that further distribution or publication of this material be discontinued immediately. Please inform us of your intentions within 30 days of receipt of this letter. If you have any questions, you may contact us at (301) 827-6639.

Sincerely yours,

Vitolis E. Vengris, D.V.M., Ph.D.  
Team Leader, Marketed Product  
Scientific and Regulatory Review Team  
Division of Epidemiology  
and Surveillance  
Center for Veterinary Medicine