DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

MAY 15 2003

James H. Schafer, D.V.M.
800 Helena Court
Fort Collins, Colorado 80524

Re: Docket No. 02P-0489

Dear Dr. Schafer:

This is a tentative response to the citizen petition (Docket No. 02P-0489) which you submitted to the Food and Drug Administration (FDA) on November 18, 2002. The citizen petition requests that the Center for Veterinary Medicine of the FDA revise its bioequivalence guidelines to harmonize with those in the European Union's guidance, *Guidelines for the Conduct of Bioequivalence Studies for Veterinary Medicinal Products.*

According to Title 21, Code of Federal Regulations, FDA is required to respond to a citizen petition within 180 days. See 21 CFR 10.30. FDA is currently considering the issues raised in your citizen petition. Because of the complex nature of the action requested, which requires careful and thorough scientific, legal and policy consultation, analysis and coordination within the agency, FDA will require additional time to issue a final response to your citizen petition. Upon our resolution of these outstanding issues, FDA will issue the final response.

Sincerely yours,

John M. Taylor, III
Associate Commissioner
for Regulatory Affairs

02P-0489

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