Congress of the United States
Washington, DC 20510

March 26, 2004

Dr. Lester M. Crawford, Acting Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
5600 Fishers Lane, Room 1471
Rockville, MD 20857

Dear Dr. Crawford:

We have reviewed the Food and Drug Administration's Notice of Opportunity for Hearing, specifically relating to certain antibiotic animal drug products listed in the *Code of Federal Regulations* (CFR), Section 558.15.

After reviewing CFR § 558.15, as incorporated by cross-reference in CFR § 558.76 and the reference to New Animal Drug Application (NADA) 141-137, there appears to be no confusion over the approval status of Bacitracin Methylene Disalicylate Single-Ingredient Type A Medicated feed additive. The administrative record clearly demonstrates that this product has had approval by your department for over thirty years.

Therefore, we would like to discuss with you the approval status of Bacitracin Methylene Disalicylate Single-Ingredient and also the approval status of oxytetracycline and neomycin fixed-combination additive. It is our understanding that the approval status of oxytetracycline and neomycin fixed-combination had been previously studied in the affirmative, and that our predecessors, Senators Jim Exon and Bob Kerrey, together with Congressmen Michael Bilirakis and Joe Barton, were fully briefed to that effect in 1996. We are writing to inquire why there seems to be newfound confusion within your agency over these listings.

We believe it is important that we discuss this matter, with all interested parties present, in order to find a resolution regarding the approval status of these drugs. Therefore, we are requesting that you schedule a meeting with our offices as soon as possible.

We appreciate your attention to this matter, and look forward to your prompt response.

Sincerely,

Elizabeth Dole

cc: Dr. Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration

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