

03-Mar-2004 09:53am From: Congressman Lee Terry

202-226-5452

T-193

P.002/002 F-662

LEE TERRY
NEBRASKA, 2ND DISTRICT



HOUSE COMMITTEE ON
ENERGY AND COMMERCE

WASHINGTON OFFICE
1524 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 228-4155

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COMMERCE, TRADE AND
CONSUMER PROTECTION

Congress of the United States
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DISTRICT OFFICE
11640 ANTON STREET, SUITE 100
OMAHA, NE 68131
(402) 387-8944

ltt21n@mail.house.gov
www.house.gov/ltt

March 3, 2004

Dr. Steven F. Sundberg, Director
FDA Center for Veterinary Medicine
MPN IV, 7519 Starfish Place
Rockville, MD 20855

Dear Director Sundberg:

I have reviewed your department's Notice of Opportunity for Hearing specifically relating to certain antibiotic animal drug products listed in the Code of Federal Regulation section §558.15.

After reviewing CFR §558.15 as incorporated by cross reference CFR §558.76 and the reference to NADA 141-137, there appears to be no confusion over the approval status of Bacitracin Methylene Disalicylate Single-Ingredient Type A Medicated feed additive. According to the administrative record, this product has had approval by your department for more than thirty years.

This is why I am concerned by your uncertainty over the approval status of this product, as noted in the August 8, 2003 edition of the Federal Register.

I would appreciate the opportunity to discuss this matter with you – as well as the approval status of oxytetracycline and neomycin fixed-combination additive. It is my understanding that the approval status of oxytetracycline and neomycin fixed-combination had been previously studied in the affirmative, and that former Senators Kerry and Exon, and Congressmen Barton and Bilirakis, were briefed in 1996. I am concerned about this confusion within the CVM.

Again, I would appreciate the chance to discuss this matter further with you at your earliest convenience. Thank you.

Sincerely,


LEE TERRY
Member of Congress

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