## **Buchanan Ingersoll**

**ATTORNEYS** 

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Division of Dockets Management (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD, 20852

## **Notice of Participation**

Docket No. 2003N-0324

Under 21 CFR part 12, please enter the participation of:

Andrew L. Winstrom, President Pennfield Oil Co. / Pennfield Animal Health Co. 14040 Industrial Road Omaha, Nebraska 68144 (402) 330-6000

Service on the above will be accepted by:

Edward John Allera, Esq.
Counsel to Pennfield Oil Co. / Pennfield Animal
Health Co.
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The following statements are made as part of this notice of participation:

A. Specific interests. Pennfield Oil Co./ Pennfield Animal Health Co. ("Pennfield") markets bacitracin methylene disalicylate, an animal drug product at issue in "Certain Antibiotic New Animal Drug Products and Use Combinations Subject to Listings in the New Animal Drug Regulations; Drug Efficacy Study Implementation; Notice of Opportunity for Hearing," published in the *Federal Register* on August 8, 2003 (68 Fed. Reg. 47332), and desires to be heard regarding all matters pertaining to the legal regulatory status of its product, (NADA 141-137).

B. Commitment to participate. "Pennfield" will present documentary evidence and/or testimony at the hearing, will otherwise fully participate in the hearing process, and will comply with the requirements of 21 CFR 12.85.

Andrew L. Winstrom, President
Pennfield Oil Co. and Pennfield Animal
Health Co.

Edward John Allera, Counsel to Pennfield Oil Co. and Pennfield Animal Health Co.