DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

ckville MD 20857

NADAs 46-592, 65-470 and 98-452

Bernard B. Brown, Ph.D.
Vice President, Research & Development
A. L. Laboratories, Inc.
452 Hudson Terrace
Englewood Cliffs, New Jersey 07632

Dear Dr. Brown:

This is in regard to your above referenced new animal drug applications for bacitracin premixes and soluble powder.

As you are aware, these products were reviewed by the NAS/NRC and were found less than "effective" for many of the claims made in the labeling. You submitted supplemental NADAs for these products, and have provided information supporting their safe and effective use for various claims.

Our normal procedure for finalizing the NAS/NRC review action follows one of two routes. For single sponsor drugs, upon completion of the necessary work and submission of revised labeling, a supplemental approval notice is published in the FEDERAL REGISTER, establishing a new or revised monograph for the drug. For multi-sponsor drugs, a Notice of Opportunity for Hearing (NOOH) is published, proposing to withdraw approval of all applications for which revised labeling is not submitted by a certain time.

In the case of bacitracin premixes and soluble powders, there are two sponsors, yourself and International Minerals & Chemical Corp., holding approval for similar products. This would normally be cause for going the NOOH route to effect NAS/NRC finalization. However, this is a resource intensive, time consuming process for both the government and the affected firms. The Bureau is committed to the principles of the Regulatory Flexibility Act and to Presidential Order 12291 which require that our regulatory processes have the minimum adverse impact. To this end, we are proposing to deviate from our normal procedures by requesting both you and International Minerals & Chemical Corp. to submit revised labeling for these bacitracin products.

We request that you submit, by October 1, 1981, supplemental applications for each of your bacitracin products. The applications should contain draft revised labeling bearing those claims which were formerly deemed "effective" or "probably effective" and later moved into the effective category by the NAS/NRC DESI Notices, as well as those claims supported by new (proprietary) safety and efficacy data. The applications should also clearly indicate the intent of the supplements as NAS/NRC finalization. The conditions of the supplemental NADA approvals will be published in the FEDERAL REGISTER in the usual manner.

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The DESI-reviewed claims which were deemed less than "effective" and for which no adequate supporting data were forthcoming will be deleted from the corresponding sections in 21 CFR, Part 500 for all bacitracin products simultaneously.

We have set a mark of January 1, 1982 for completion of the DESI action for bacitracin premixes and soluble powders. We recognize that you are still working to support additional proprietary claims. This action will not effect our review of the proprietary information you have submitted in support of the new claims you are seeking.

If you have reservations about this finalization approach, we request that you convey them to us by September 1, 1981. Unless both you and International Minerals & Chemical Corp. agree with this approach and submit the requested supplements, our only remaining option will be to publish the NOOH. We are available to discuss any questions which you may have. We await the receipt of appropriate supplements to your respective NADAs.

Sincerely yours,

Lonnie W. Luther

Lonnie W. Luther, Ph.D.
Chief, Metabolic Products Branch
Division of Drugs for Avian Species
Bureau of Veterinary Medicine