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April 21, 2003

FAP 2234
Natamycin

Dr George Graber, Ph.D.
Director
Division of Animal Feeds
Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Place
Rockville, MD 20857

Dear Dr. Graber:

In answer to your letter dated April 14, 2003, we have the following comments.

You are correct, there were no typographical errors as we indicated in our letter received by you on March 20, 2003.

We asked for the clearance to use ten grams (10g) of natamycin per ton of broiler chicken feed. Our submitted label states ten grams (10g) of natamycin. Our intention has always been to use ten grams (10g) of natamycin per ton of broiler chicken feed. Since raw ingredients vary slightly from batch to batch, the following is done to achieve exactly ten grams of natamycin activity in each pound of N-SURE® premix made.

1. Each batch of raw natamycin is assayed to determine the "as-is" percentage of the natamycin. The batch of natamycin used in our experiments assayed at 88.56%.
2. We divide ten grams (our target amount) by the assayed percentage of the raw natamycin (88.56%) to give us the number of grams of the raw natamycin (11.292 gms) to include in each pound of N-SURE® premix to give us the ten grams of activity we claim.

3. The batch of N-SURE® premix is then assayed to verify that we achieved our target concentration (10g per pound).

We have revised our label to include your recommendations by eliminating one caution statement and combining that statement into our directions for use. We have added a telephone number after the company address. A copy of this revised label is attached. If there are any questions please call me at 307-742-9699.

Sincerely,

Franklin Carter
Consultant to Arkion L.S.