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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

VIA FEDERAL EXPRESS

May 29, 2002

Our Reference Number: FEI3002179593

Mr. James C. Robison, Chief Executive Officer
Walco International, Inc.
520 South Main Street
Grapevine, TX 76051-5365

Dear Mr. Robison,

On March 25 and 26, 2002, the U.S. Food and Drug Administration (FDA) inspected your facility located at 979 E. Bardsley, Tulare, CA. The inspection revealed that this facility sold and shipped Pharmacia & Upjohn brand Neomix AG325 (neomycin sulfate), a Category II Type A Medicated Article, to [REDACTED] and [REDACTED]. Neither of these firms has a valid FDA Medicated Feed Mill License. These violations were reported to the firm on Form FDA 483, which was provided to Roger W. Fanjul, Division Manager, at the close of the inspection (copy enclosed). Moreover, a previous FDA inspection revealed that your firm also sold Pharmacia & Upjohn brand Neomix AG325 to [REDACTED] which also does not hold a valid FDA Medicated Feed Mill License.

Pursuant to Section 512 of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 360b(a)(1), a new animal drug is deemed unsafe, and therefore, adulterated under Section 501(a)(5), 21 U.S.C. § 351(a)(5), if it is removed from a distributor's establishment for use in the manufacture of animal feed, unless at the time of such removal, the distributor has an unrevoked written statement from the consignee of the drug, or notice from the Secretary of Health and Human Services to the effect that, with respect to the use of such drug in animal feed, such consignee (i) holds a license and possesses current approved labeling for such drug in animal feed or (ii) will, if the consignee is not a user of the drug, ship such drug only to a holder of a license. Accordingly, removal of a Type A Medicated Article from your facility for the intended use as a free-choice feed by the above-

referenced firms violates Section 501(a)(5) of the Act and causes the new animal drug to be adulterated.

As a distributor of materials intended for animal feed use, you are responsible for assuring that your overall operation and the products you distribute are in compliance with the law. This includes ensuring that each site where your firm handles Type A Medicated Articles adheres to the requirement not to ship to unlicensed or unauthorized parties.

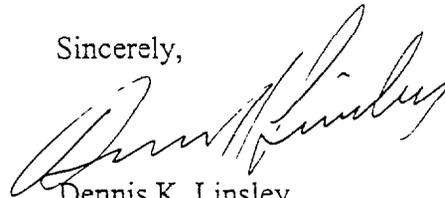
You should take prompt action to establish procedures whereby such violations do not recur. Failure to make immediate and lasting corrections may result in regulatory action without further notice, such as seizure and/or injunction.

Please advise this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps that you have taken to prevent recurrence of the cited violations. Please direct your response to:

Warren E. Savary, Compliance Officer
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502.

You may FAX your response to Mr. Savary at (510) 337-6707. Should you have any questions, Mr. Savary can be reached at (510) 337-6821.

Sincerely,



Dennis K. Linsley
District Director
San Francisco District

cc: Mr. Roger W. Fanjul, Division Manager
Walco International, Inc.
979 E. Bardsley Avenue
Tulare, CA 93274