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Food and Drug Administration  
Denver District Office  
Bldg. 20-Denver Federal Center  
P.O. Box 25087  
6<sup>th</sup> Avenue & Kipling Street  
Denver, Colorado 80225-0087  
Telephone: 303-236-3000  
FAX: 303-236-3100

October 15, 2001

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. LaMar G. Clements  
President  
Walton Feeds West, Inc.  
P.O. Box 52  
Cache Junction, Utah 84304

Ref. #: DEN-02-01

Dear Mr. Clements:

On July 25, 2001, the U.S. Food and Drug Administration made an inspection of your feed supplement manufacturing facility. The inspection revealed that this facility has sold and shipped a Type A Medicated Article (Lasalocid/Bovatec 68) to [REDACTED], Utah, which does not have a valid FDA Medicated Feed Mill License.

Removal of a Type A Medicated Article from your facility for the intended use as a free-choice feed by Winn, Inc., is a violation of Section 501(a)(5) of the Federal Food, Drug and Cosmetic Act (the Act), and causes the new animal drug to be unsafe within the meaning of Section 512 of the Act, and therefore, adulterated. The drug is unsafe, unless you have in your possession an unrevoked, written statement from the consignee, or notice from the Secretary (DHHS), to the effect that, with respect to the use of such drug in animal feed, such consignee holds a license and has in its possession current approved labeling for such drug in animal feed; or will, if the consignee is not a user of the drug, ship such drug only to a holder of a license.

As a manufacturer of materials intended for animal feed use, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. This includes assuring that each site where your firm handles Type A Medicated Articles adheres to the requirement not to ship to unlicensed or unauthorized parties. At the conclusion of the inspection, you were also advised of this requirement by the Investigator.

You should take prompt action to correct the above violation and 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.

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You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law.

Your response should be sent to Tom Warwick, Compliance Officer, Food and Drug Administration, P.O. Box 25087, Denver, Colorado, 80225-0087. He may be reached at (303) 236-3054 if you have any questions about this matter.

Sincerely,

*Howard E. Monahan, Acting for*

Thomas A. Allison  
District Director