DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 22 2005

NADA: 138-952

Melissa F. Veenhuizen, DVM, MS
Manager, Regulatory –Surveillance and Compliance
Elanco Animal Health
2001 W. Main Street, DC GL21
Greenfield, IN 46140

RE: Maxiban® (narasin, nicarbazin); promotional piece AI9332 (NADA 138-952)

Dear Dr. Veenhuizen:

The Division of Surveillance (DOS) has reviewed a detailer entitled "Maxiban®: Maximizing Performance" (AI9332) for Maxiban® submitted by Elanco Animal Health under cover of form FDA 2301 dated March 15, 2005. This promotional piece contains unapproved new animal drug claims and fails to reveal risk information, causing the drug to be adulterated under section 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act) and misbranded under sections 502(a) and 201(n) of the Act.

Background

Maxiban® is a Type A medicated article containing 36 grams per pound of narasin and 36 grams per pound of nicarbazin. It is approved for use in broiler chickens solely for the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunette, E. mivati, and E. maxima*. It is mixed in feed to provide a dosage of 27 to 45 grams per ton each of narasin and nicarbazin.

The FDA-approved labeling for Maxiban® contains the following statement in a **Warning** section:

> Feeds containing Maxiban must be withdrawn 5 days prior to slaughter.

The FDA-approved labeling also contains the following statements in a **Caution** section:

> Nicarbazin medicated broilers may show reduced heat tolerance if exposed to high temperature and high humidity. Provide adequate drinking water and ventilation during these periods. **Do not allow adult turkeys, horses or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Do not feed to laying hens.**

Unapproved New Animal Drug Claims

The detailer (AI9332) presents data in the form of charts with these headings in bold type: **"Maxiban improves feed conversion"; "Maxiban increases average daily gain"; "Maxiban shows reduced heat-stress mortality"; and "Maxiban increases weight gain."** The drug's only approved indication is that of prevention of coccidiosis caused by *Eimeria spp.* It is not approved for improving feed conversion, increasing daily gain, reducing heat-stress mortality, or increasing weight gain. The statements made in the detailer are unapproved new animal drug claims because they suggest that Maxiban® can enhance the normal physiologic performance of producers' flocks even in the absence of disease or illness. Claims associated with derived production efficiency benefits that are made without language that explains that the benefits are derived from the approved use -- the prevention of coccidiosis -- imply that the product acts anabolically and gives the impression that the weight gain, improved feed efficiency, etc., are the direct result of treatment with the product regardless of whether or not the birds were parasitized. Because the detailer does not conform to the approved application for Maxiban, the drug is unsafe under section 512 of the Act and thus adulterated under section 501(a)(5) of the Act.

We note that if the claims are modified with language such as "by prevention of coccidiosis, birds treated with Maxiban® are able to perform to their full genetic potential, thus gaining weight and utilizing feed efficiently as any normal, healthy bird would," the claims would be within the scope of the approved application.

Failure to reveal risk information

Under section 502(a) of the Act, a drug shall be deemed to be misbranded if its labeling is false or misleading in any particular. Section 201(n) of the Act states that "in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual."

The detailer is misleading because it fails to include risk information as necessary to qualify the safety and effectiveness claims for Maxiban®. As noted above, the ingestion of narasin by turkeys and horses can be fatal. Maxiban® has a 5 day withdrawal period for broiler chickens, and should not be fed to laying hens. This is important in preventing residues in food for human consumption. These are important facts that producers should be aware of, and the absence of a brief statement regarding these risks may lead to the potentially unsafe use of Maxiban®. The detailer therefore causes the drug to be misbranded under sections 502(a) and 201(n) of the Act.

Conclusion and Requested Action

The detailer contains unapproved new animal drug claims for Maxiban® and fails to reveal risk information associated with the use of Maxiban®. Accordingly, the drug is adulterated under section 501(a)(5) and misbranded under sections 502(a) and 201(n) of the Act.

DOS requests that Elanco Animal Health immediately cease the dissemination of the Maxiban® promotional piece described above, and any that may contain similar information. Future promotional materials should adequately address risk information, and claims associated with derived production efficiency benefits should not be made without language that explains that the benefits are derived from the prevention of coccidiosis. Please submit a written response within 30 days of receipt of this letter describing your intent to comply with this request. Please direct your response to me at the Food and Drug Administration, Division of Surveillance, HFV-216, 7519 Standish Place, Rockville, MD 20855. We remind you that only written communications are official.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to see that your promotional materials for Maxiban®, as well as other Elanco Animal Health products, comply with the requirements of the Act and FDA implementing regulations.

Sincerely yours,

Mohammad I. Sharar, DVM, M.Sc.
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Post-Approval Review Team, HFV-216
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