



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 17 2000

NADA 141-081

Ms. Nancy Thompson-Brown
Regulatory Compliance Specialist
Schering-Plough Animal Health Corporation
1095 Morris Avenue
Union, NJ 07083

Dear Ms. Thompson-Brown:

We refer to your submission of promotional materials for Orbox Tablets (orbifloxacin) under Form FDA 2301, dated October 26, 2000. Specifically, we refer to the materials identified as SPAH-OR-29 "THE BUCK STOPS HERE!," and SPAH-OR-31 "SAVINGS AROUND THE CLOCK." We also call attention to your website for Orbox, accessed through www.sp-animalhealth.com or www.spah.com. We have reviewed the printed materials and your website for Orbox on November 3, 2000, and conclude that your promotion of Orbox conveys misleading messages.

In your submitted materials, there are several benefits listed for using Orbox such as "Documented comparative efficacy in: feline and canine wounds..abscesses and canine cystitis" and "Proven efficacy." Also, your link from the Orbox homepage to its product information page discloses information about the efficacy and advantages of using Orbox. Examples include "efficacy demonstrated in canine urinary cystitis and dermal infections in dogs and cats" and "Demonstrated safe in adult dogs and adult cats at up to 5 times the maximum intended clinical dose for 30 days. Demonstrated safe in 12-week old kittens at more than 3 times the maximum intended clinical dose for 32 days." Promotional materials should present information relating to contraindications, precautions, and side effects in a manner reasonably comparable to the presentation of information on the effectiveness of the drug, otherwise they are construed to be misleading. Your promotion does not present a fair balance of information about Orbox. The promotional content contains efficacy claims but fail to provide any information on the risks associated with the use of Orbox. For example, there is a contraindication against use in immature dogs and a precaution against use in animals known to have a suspected central nervous system disorder. Directing readers to the full prescribing information (i.e., the approved package insert) in your print materials is not sufficient to provide the necessary risk information.

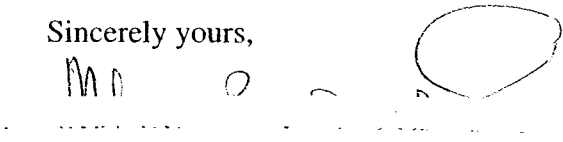
Also, the Orbox homepage link to its product information page uses the following statements (as mentioned above) to characterize Orbox: "Demonstrated safe in adult dogs and adult cats at up to 5 times the maximum intended clinical dose for 30 days."; and "Demonstrated safe in 12-week old kittens at more than 3 times the maximum intended clinical dose for 32 days." However, Orbox was found to induce arthropathy in young, rapidly growing beagles, and Orbox was found to produce mild gastrointestinal effects (at 3x

and 5x) in young adult cats. None of this information was included. The selective use of favorable safety data in this fashion minimizes the safety and is misleading.

Additionally, in your "THE BUCKS STOP HERE!" promotional piece the cost comparisons between Orbax and Baytril based on the lowest recommended dosage and a 14-day course of treatment are misleading. You compare the lowest recommended dose, i.e., 2.5 mg/kg of Orbax and 5 mg/kg of Baytril in cats. There is only a single dose of 5 mg/kg now recommended for Baytril in cats. Furthermore, the prescribed dosage for Orbax in cats and dogs, and Baytril in dogs will vary from case-to-case depending on such factors as the severity and nature of the infection, the susceptibility of the causative organism(s) to the two drugs, and the integrity of the patient's host-defense mechanisms. However, none of this was disclosed along with your cost comparisons. Without further qualification, the comparisons are misleading.

We request that you stop using the cited material in the promotion of your product and inform us of your intentions as soon as possible or in any event within 30 days of the receipt of this letter. If you have any questions, please contact us 301-827-6642.

Sincerely yours,



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