DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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NADA 141-081

Nancy Thompson-Brown
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Schering-Plough Animal Health Corporation
1095 Morris Avenue
Union, New Jersey 07083-1982

Dear Ms. Brown:

This letter is in reference to your Drug Experience Report dated August 6, 2002, concerning Orbax tablets, NADA 141-081. The submission includes a Trade Ad coded SPAH-OR-33 and appears in various veterinary trade magazines.

The advertisement makes claims discussing the benefits of the product, such as:

- "When prescribing fluoroquinolones, side effects like feline retinal degeneration can be a concern. But they don't have to be. Clinical studies show that Orbax® has an excellent ocular safety profile...."
- "...get all the benefits of a proven antibiotic with uncompromised safety."
- "...proven all-around performer."
- " Find out why so many vets have trusted Orbax for so many years."

However, the body of the advertisement lacks any information relating to side effects and contraindications of the product.

Orbax's approved labeling lists "arthropathy" and "hypersensitivity to quinolones" in its contraindications section, includes a caution for use in "animals with known or suspected central nervous system disorders," and includes "mild gastrointestinal effects (soft feces)", "emesis," "diarrhea," and "reduced food consumption with subsequent reduced bodyweight" as side effects in its Target Animal Safety section. Although the advertisement includes a required reference to a brief summary that appears many pages away in the journal, presenting risk information in this manner is not in accordance with FDA's prescription drug advertising regulations. Under 21 CFR § 202.1(e)(3)(i), at a minimum an advertisement must contain a concise discussion of the appropriate qualification or pertinent risk information and a prominent reference to a more complete discussion elsewhere in the advertisement. Moreover, while the required risk information may be contained elsewhere in the advertisement, if there is an appropriate reference and concise summary, it may not be somewhere outside the advertisement, such as in a distinct place in a journal that is separated by many pages.

The Orbax advertisement also makes the following comparative claim:

> "When you compare the labels of other leading brands, you'll also see that Orbax lists the fewest side effects in dogs and cats."

This claim is false since the side effects listed above for Orbax are similar to the side effects for other comparable fluoroquinolone antimicrobials such as marbofloxacin and difloxacin hydrochloride (21 CFR § 202.1(e)(6)(ii)).

Also, the Orbax advertisement makes the claim that:

> "When prescribing fluoroquinolones, side effects like feline retinal degeneration can be a concern. But they don't have to be. Clinical studies show that Orbax® has an excellent ocular safety profile -- one that has been substantiated with over five years of field use."

This claim is false or misleading. FDA is not aware of any data supporting the claim that clinical studies show an excellent ocular safety profile. In addition, the claim is contradicted by a review of the adverse event database (through 2000) on the CVM website (http://www.fda.gov/cvm/index/ade/ade_web_rpts87_00.htm), which contains reports submitted for "blindness (1)," "partial blindness (1)," temporary blindness (1)," and "retina abnormal (1)." associated with the use of Orbax. Furthermore, our DER adverse event reports for Orbax shows 12 cases of blindness listed in the database with a drug causality assessment of "possible."

We also note that the advertisement includes the tradename for the product, but fails to display the established name of the drug (21 CFR § 202.1(b)(1)). Inclusion of the established name of the drug in the brief summary alone, which is not contiguous to the advertisement, is not sufficient.

You should immediately stop dissemination of this and any other similar future promotional pieces. Please respond within 15 days of the receipt date of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours,

Lynn O. Post, D.V.M., Ph.D., DABVT
Director
Division of Surveillance
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