FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 101-479

BANAMINE® Injectable Solution
(flunixin meglumine)

"... indicated for the alleviation of inflammation and pain associated with musculoskeletal disorders and for alleviation of visceral pain associated with colic in horses."

Sponsored by:

SCHERING-PLOUGH ANIMAL HEALTH

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FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

NADA Number: 101-479

Sponsor: Schering-Plough Animal Health Corporation
1095 Morris Ave.
Union, New Jersey 07083-1982

Established Name: flunixin meglumine

Tradename: BANAMINE® Injectable Solution - 50 mg/mL

Marketing Status: This is a prescription product and will include the caution statement as follows: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Supplement Effect: This supplement provides for an additional statement added to the Precaution section of the labeling and a heading change on the label from Warning to Adverse Reactions to the previously approved product labeling for BANAMINE® Injectable Solution.

II. INDICATIONS FOR USE

BANAMINE® Injectable Solution is recommended for the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse. Its is also recommended for the alleviation of visceral pain associated with colic in the horse.

III. DOSAGE FORM, ROUTE OF ADMINISTRATION, AND RECOMMENDED DOSAGE

A. *Dosage Form*: BANAMINE® Injectable Solution is a sterile solution available in 50 mL, 100 mL and 250 mL multidose vials. Each milliliter contains 50 mg flunixin as the meglumine salt.

B. *Route of Administration*: Intramuscular or intravenous injection

C. *Approved Dose*: The recommended dose for musculoskeletal disorders is 0.5 mg per pound (1 ml/100 lbs) of body weight once daily. Treatment may be given by intravenous or intramuscular injection and repeated for up to 5 days. The recommended dose for alleviation of pain associated with equine colic is 0.5 mg per pound of body weight. Intravenous administration is recommended for prompt relief. Treatment may be repeated when signs of colic recur.

IV. EFFECTIVENESS

Additional effectiveness studies were not necessary for the proposed label changes.

V. ANIMAL SAFETY

Additional safety studies were not necessary for the proposed label changes.

VI. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA comply with the requirements of section 512 of the Act and demonstrate that flunixin meglumine injection, when used under the proposed conditions of use, is safe and effective for the alleviation of inflammation and pain associated with musculoskeletal disorders when administered intramuscularly or intravenously at 0.5 mg/lb daily for up to 5 days and for the alleviation of visceral pain associated with colic when administered intravenously at 0.5 mg/lb as needed.

Labeling restricts this drug to use by or on the order of a licensed veterinarian.

In accordance with 21 CFR 514.106(b)(2)(ix), this is a category II change. The approval of this change did not require a reevaluation of the safety and effectiveness data in the parent application.

Under section 512(c)(2)(F)(iii) of the FFDCA, this approval for non food producing animals does not qualify for marketing exclusivity because the supplemental application does not contain substantial evidence of the effectiveness of the drug involved, or any studies of animal safety required for the approval and conducted or sponsored by the applicant.

VII. APPROVED PRODUCT LABELING

Facsimile package insert for the 50 mL, 100 mL, and 250 mL vials and box carton is enclosed.