Date of Approval: April 25, 2006

# FREEDOM OF INFORMATION SUMMARY

NADA 131-918

TRIBRISSEN 400 Oral Paste

trimethoprim/sulfadiazine

For control of bacterial infections during treatment of acute strangles, respiratory tract infections, acute urogenital infections, wound infections, and abscesses.

Sponsored by:

Schering-Plough Animal Health Corp.
556 Morris Ave.
Summit, NJ 07901

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## *1. GENERAL INFORMATION:*

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|---|---|---|
| a. | File Number: | NADA 131-918 |
| b. | Sponsor: | Schering-Plough Animal Health Corp.<br>556 Morris Ave.<br>Summit, NJ 07901<br><br>Drug Labeler Code: 000061 |
| c. | Established Name: | trimethoprim/sulfadiazine |
| d. | Proprietary Name: | TRIBRISSEN 400 Oral Paste |
| e. | Dosage Form: | Paste |
| f. | How Supplied: | DIAL-A-DOSE syringe |
| g. | How Dispensed: | Rx |
| h. | Amount of Active Ingredients: | Each gram contains 67 mg trimethoprim and 333 mg sulfadiazine |
| i. | Route of Administration: | Oral |
| j. | Species/Class: | Horses |
| k. | Recommended Dosage: | 3.75 g per 110 lbs (50 kg) body weight once daily given orally. |
| l. | Pharmacological Category: | Antibacterial |
| m. | Indications: | For the control of bacterial infections during treatment of acute strangles, respiratory tract infections, acute urogenital infections, wound infections, and abscesses. |
| n. | Effect of Supplement: | This is a regulatory supplement requesting changes recommended by the Division of Surveillance and ONADE. The labeling supplement adds post-approval experience information, revises the warning statement, and updates the label format. |

***2. EFFECTIVENESS:***

***a. Dosage Characterization:*** New information was not required for this supplement.

**b. *Substantial Evidence:*** New information was not required for this supplement.

***3. TARGET ANIMAL SAFETY:***

The following Post Approval Experience was added to the label: Horses have developed diarrhea during TRIBRISSEN 400 Oral Paste treatment, which could be fatal. If fecal consistency changes during TRIBRISSEN 400 Oral Paste therapy, discontinue treatment immediately and contact your veterinarian.

***4. HUMAN SAFETY:***

This drug is intended for use in horses, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: "Keep out of reach of children. Do not use in horses intended for human consumption."

***5. AGENCY CONCLUSIONS:***

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that TRIBRISSEN 400 Oral Paste when used under the labeled conditions of use is safe and effective for the control of bacterial infections during treatment of acute strangles, respiratory tract infections, acute urogenital infections, wound infections, and abscesses.

The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise is needed to diagnose and treat bacterial infections in horses.

This approval for does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

According to the Center's supplemental approval policy (21 CFR 514.106), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

There were no patents submitted with this application.

**6. *ATTACHMENTS:***

Facsimile labeling is attached as indicated below:

Carton Front Panel

Package Insert