Date of Approval: November 15, 2001

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 141-064

Pulmotil® 90 tilmicosin

For Revision of the Approved Pulmotil® 90 tilmicosin Labeling 1) removal of the MIC chart; 2) additions to the Pharmacology section of the label; 3) additional CAUTION that discourages continuous use for more than 21 days and limits use of each VFD form to 90 days. Changes to the VFD are inclusion of the additional CAUTION like the label and 2) addition of a 90-day maximum for the expiration of the VFD.

SPONSORED BY:

Elanco Animal Health

I. GENERAL INFORMATION

NADA Number: 141-064

Sponsor: Elanco Animal Health
Lily Corporate Center
Indianapolis, Indiana 46285

Established Name: tilmicosin phosphate

Trade Name: Pulmotil® 90 tilmicosin

Marketing Status: Veterinary Feed Directive (VFD)

Effect of Supplement: Changes to the label are 1) removal of the MIC chart; 2) additions to the Pharmacology section of the label; 3) additional CAUTION that discourages continuous use for more than 21 days and limits use of each VFD form to 90 days. Changes to the VFD are inclusion of the additional CAUTION like the label and 2) addition of a 90-day maximum for the expiration of the VFD.

II. INDICATIONS FOR USE

For the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

III. DOSAGE

A. Dosage Form:

Type A Medicated Article

B. Route of Administration:

Oral, in feed

C. Recommended Dosage:

Fed continuously at 181 to 363 grams tilmicosin per ton (200 to 400 ppm) of type C medicated feed as the sole ration for a 21-day period, beginning 7 days before an anticipated disease outbreak.

IV. EFFECTIVENESS

No further effectiveness data were required from the original approval dated December 27, 1996.

V. ANIMAL SAFETY

No further target animal safety data were required from the original approval dated December 27, 1996.

VI. HUMAN SAFETY

No further human food safety data were required from the original approval dated December 27, 1996.

VII. AGENCY CONCLUSIONS

The information submitted in support of this supplemental NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and implementing regulations at Part 514 of Title 21, Code of Federal Regulations (21 CFR 514) for Pulmotil® 90 tilmicosin for swine, to allow for the revisions of the labeling and VFD.

In accordance with 21 CFR 514.106(b)(2), this is a Category II change which did not require a reevaluation of the safety or effectiveness data in the parent application.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant impact on human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Under section 512(c)(2)(F)(iii) of the FFDCA, this approval for food-producing animals does not qualifies for marketing exclusivity beginning on the date of approval because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval of the application and conducted or sponsored by the applicant.

VIII. APPROVED PRODUCT LABELING

Pulmotil® 90 tilmicosin Type A Medicated Article label

Medicated Type B and C Bluebird labels

Veterinary Feed Directive

Copies of applicable labeling may be obtained by writing to:

Freedom of Information Staff (HFI-35)
Room 12A16
5600 Fisher's Lane
Rockville, MD 20857