

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Notice of Approval of Supplemental New Animal Drug Application; Tilmicosin

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is providing notice that it has approved a supplemental new animal drug application (NADA) filed by Elanco Animal Health. The approved NADA provides for the veterinary prescription use of an injectable solution of tilmicosin phosphate for respiratory disease in cattle and sheep. This supplemental NADA adds user safety information to product labeling.

**FOR FURTHER INFORMATION CONTACT:** Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: [joan.gotthardt@fda.gov](mailto:joan.gotthardt@fda.gov).

**SUPPLEMENTARY INFORMATION:** Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 140-929 for MICOTIL 300 (tilmicosin phosphate), an injectable solution available by veterinary prescription for use in the treatment and control of respiratory disease in cattle and in the treatment of respiratory disease in sheep. This supplemental NADA adds user safety information to product labeling related to the mechanism of toxicity and medical intervention. In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(i)) and part 514 (21 CFR part 514) in §§ 514.105(a)

and 514.106(a), the Center for Veterinary Medicine is providing notice that this supplemental NADA is approved as of December 2, 2005. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and § 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA 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 effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: December 8, 2005.

**Bernadette Dunham,**

*Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

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