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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Tilmicosin Phosphate Injection for Sheep; Availability of Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of effectiveness and target animal safety data that may be used in support of a new animal drug application (NADA) or supplemental NADA for veterinary prescription use of tilmicosin phosphate injection for treatment of bacterial pneumonia in sheep. The data, contained in Public Master File (PMF) 5673, were compiled under National Research Support Project-7 (NRSP-7), a national agricultural research program for obtaining clearances for use of new drugs in minor animal species and for special uses.

ADDRESSES: Submit NADA's or supplemental NADA's to the Document Control Unit (HFV-199), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7569.

SUPPLEMENTARY INFORMATION: Tilmicosin phosphate injection, used for the treatment of sheep for bacterial pneumonia, is a new animal drug under section 201(v) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(v)). As a new animal drug, tilmicosin phosphate is subject to section 512 of the act (21 U.S.C. 360b), requiring that its uses in sheep be the subject of an approved NADA or supplemental NADA. Sheep are a minor species under § 514.1(d)(1)(ii) (21 CFR 514.1(d)(1)(ii)).

PMF 5673

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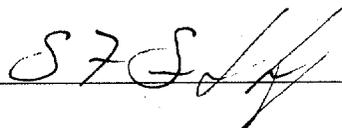
The NRSP-7 Project, Southern Region, University of Florida, Gainesville, FL 32610, has provided effectiveness and target animal safety data for veterinary prescription use of tilmicosin phosphate injection in sheep for treatment of bacterial pneumonia due to *Pasteurella (Mannheimia) haemolytica*. These data are contained in PMF 5673.

Under 21 CFR 25.15(d) and § 25.33(d)(4) (21 CFR 25.33(d)(4)), sponsors of NADA's and supplemental NADA's for drugs in minor species, including wildlife and endangered species, are categorically excluded from the requirement to prepare an environmental assessment or an environmental impact statement when the drug has been approved for use in another or the same species where similar animal management practices are used. The categorical exclusion applies unless, as in § 25.21 (21 CFR 25.21), extraordinary circumstances exist that indicate that the proposed action may significantly affect the quality of the human environment. Therefore, based upon information available, FDA agrees that when the application is submitted, the applicant may claim a categorical exclusion under § 25.33(d)(4) provided that the applicant can state that to the best of the applicant's knowledge, as in § 25.21, no extraordinary circumstances exist. It is assumed that the applicant has made a reasonable effort to determine that no extraordinary circumstances exist.

Sponsors of NADA's or supplemental NADA's may, without further authorization, reference the PMF to support approval of an application filed under § 514.1(d). An NADA or supplemental NADA must include, in addition to reference to the PMF, animal drug labeling and other information needed for approval, such as: Data supporting extrapolation from a major species in which the drug is currently approved or authorized reference to such data; data concerning manufacturing methods, facilities, and controls; data concerning human food safety; and information addressing potential environmental impacts of the manufacturing process. Persons desiring more information concerning the PMF or requirements for approval of an NADA or supplement may contact Naba K. Das (address above).

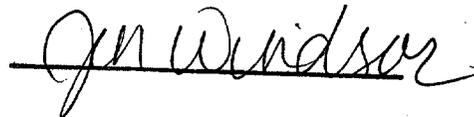
In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers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

Dated: 7/25/00
July 25, 2000



Stephen F. Sundlof
Director
Center for Veterinary Medicine

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL



[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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