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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Tylosin Tartrate for Foulbrood in Honeybees; Availability of Data**

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of effectiveness, target animal safety, human food safety, and environmental safety data that may be used in support of a new animal drug application (NADA) or supplemental NADA for use of tylosin tartrate for the control of American foulbrood (*Paenibacillus larvae*) in honeybees. The data, contained in Public Master File (PMF) 5783, 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 minor uses.

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

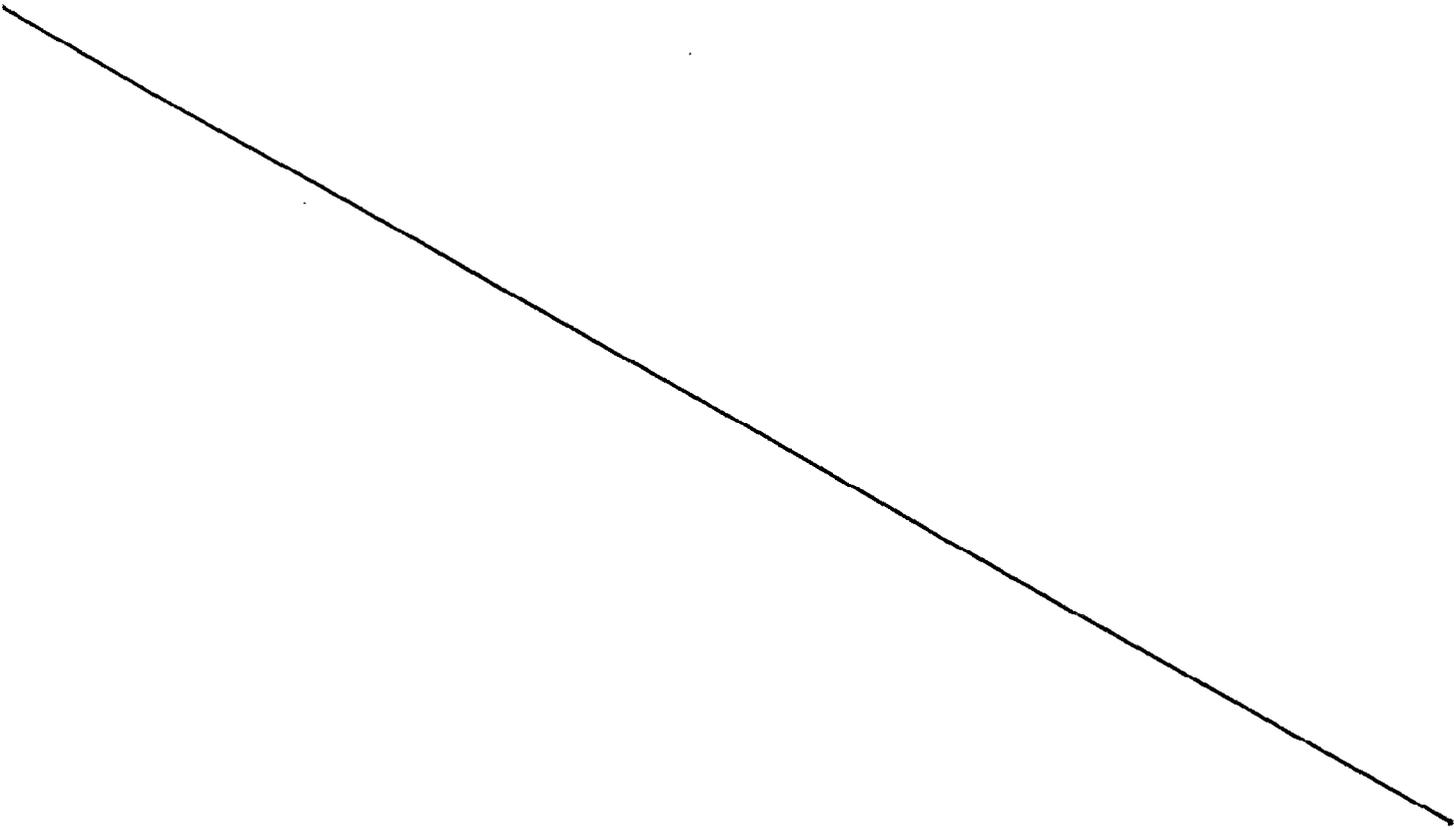
**FOR FURTHER INFORMATION CONTACT:** Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: [jgotthar@cvm.fda.gov](mailto:jgotthar@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** Tylosin tartrate soluble powder used for the control of American foulbrood (*P. larvae*) in honeybees 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, tylosin tartrate is subject to section

512 of the act (21 U.S.C. 360b) , requiring that its uses be the subject of an approved NADA or supplemental NADA. Honeybees are a minor species under § 514.1(d)(1)(ii) (21 CFR 514.1(d)(1)(ii)).

The NRSP-7 Project, western region, University of California, Davis, CA 95616, has provided target animal safety, effectiveness, human food safety, and environmental safety data for use of tylosin tartrate soluble powder for the control of American foulbrood in honeybees. These data, contained in PMF 5783, were reviewed by FDA and found satisfactory to support those aspects of an original or supplemental NADA.

Sponsors of NADAs or supplemental NADAs may, without further authorization, reference the PMF 5783 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; and data concerning manufacturing methods, facilities, and controls. Persons desiring more information concerning PMF 5783 or requirements for approval of an NADA or supplement may contact Joan C. Gotthardt (see **FOR FURTHER INFORMATION CONTACT**).

Dated: 7/27/04  
July 27, 2004.

SFS/A

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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