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.

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 larva*e) 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*.

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: July 27, 2004.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 04–17628 Filed 8–2–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0283]

Draft Guidance for Industry: Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#171) entitled ''Waivers of *In Vivo* Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles.'' This draft guidance describes the procedures that the agency recommends for the review of requests for waiver of in vivo demonstration of bioequivalence for generic soluble powder oral dosage form products and Type A medicated articles.

DATES: Submit written or electronic comments on the draft guidance by October 18, 2004, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time. Written comments on the information collection provisions must be received by October 4, 2004.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the draft guidance and collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft guidance and collection of information to *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Technical issues: Marilyn Martinez, Center for Veterinary Medicine (HFV- 130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7577, e-mail: *mmartin1@cvm.fda.gov*.

Administrative issues: Lonnie Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Center for Veterinary Medicine (CVM) has written this guidance to address a perceived need for agency guidance in its work with the animal health industry. This draft guidance describes the procedures that the agency recommends for the review of requests for waiver of in vivo demonstration of bioequivalence for generic soluble powder oral dosage form products and Type A medicated articles. As CVM develops policies on waivers involving other categories of animal drugs, it will issue additional guidance.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C.