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]

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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.

3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles

Description: The Generic Animal Drug and Patent Term Registration Act (GADPTRA) of 1988 permitted generic drug manufacturers to copy those pioneer drug products that were no longer subject to patent or other marketing exclusivity protection. The approval for marketing these generic products is based, in part, upon a demonstration of bioequivalence between the generic product and pioneer product. This guidance clarifies circumstances under which FDA believes the demonstration of bioequivalence required by the statute does not need to be established on the basis of in vivo studies for soluble powder oral dosage form products and Type A medicated articles. The data submitted in support of the waiver request are necessary to validate the waiver decision.

The requirement to establish bioequivalence through in vivo studies (blood level bioequivalence or clinical endpoint bioequivalence) may be waived for soluble powder oral dosage form products or Type A medicated articles in either of two alternative ways. A biowaiver may be granted if it can be shown that the generic soluble powder oral dosage form product or Type A medicated article contains the same active and inactive ingredient(s) and is produced using the same manufacturing processes as the approved comparator product or article. Alternatively, a biowaiver may be granted without direct comparison to the pioneer product's formulation and manufacturing process if it can be shown that the active pharmaceutical ingredient(s) (API) is the same as the pioneer product, is soluble, and that there are no ingredients in the formulation likely to cause adverse pharmacologic effects. For the purpose of evaluating soluble powder oral dosage form products and Type A medicated articles, solubility can be demonstrated in one of two ways: ''USP definition'' approach or ''Dosage adjusted'' approach.

The respondents for this collection of information are pharmaceutical companies manufacturing animal drugs. FDA estimates the burden for this collection of information as follows in tables 1 and 2 of this document. The source of the above data is records of generic drug applications over the past 10 years.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR WATER SOLUBLE POWDERS[1]

	No. of Respondents	Annual Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
Same formulation/ manufacturing process approach	1	1	1	5	5
Same API/ solubility approach	5	5	5	10	50
Total Burden Hours					55

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR TYPE A MEDICATED ARTICLES[1]

	No. of Respondents	Annual Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
Same formulation/ manufacturing process approach	2	2	2	5	10
Same API/ solubility approach	10	10	10	20	200

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR TYPE A MEDICATED ARTICLES[1]—Continued

	No. of Respondents	Annual Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
Total Burden Hours					210

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Significance of Guidance

This draft level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this draft guidance document. Two paper copies of any comments are to be submitted, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Copies of the draft guidance document entitled ''Waivers of *In Vivo* Demonstration of Bioequivalence of Certain Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles'' may be obtained from the CVM home page at *http://www.fda.gov/cvm* and from the Division of Dockets Management Web site *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: July 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Voluntary Customer Satisfaction Surveys to Implement Executive order 12862 in the Substance Abuse and Mental Health Services Administration (SAMHSA)—OMB No. 0930–0197; Extension)—Executive Order 12862 directs agencies that ''provide significant services directly to the public'' to ''survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services.'' SAMHSA provides significant services directly to the public, including treatment providers and State substance abuse and mental health agencies, through a range of mechanisms, including publications, training, meetings, technical assistance and web sites. Many of these services are focused on information dissemination activities. The purpose of this submission is to extend the existing generic approval for such surveys.

The primary use for information gathered is to identify strengths and weaknesses in current service provisions by SAMHSA and to make improvements that are practical and feasible. Several of the customer satisfaction surveys expected to be implemented under this approval will provide data for measurement of program effectiveness under the Government Performance and Results Act (GPRA). Information from these customer surveys will be used to plan and redirect resources and efforts to improve or maintain a high quality of service to health care providers and members of the public. Focus groups may be used to develop the survey questionnaire in some instances.

The estimated annual hour burden is as follows:

Type of data collection	Number of respondents	Responses/respondent	Hours/response	Total hours
Focus groups	150	1	2.50	375
Self-administered, mail, telephone and e-mail surveys	16,000	1	.33	5,280
Total	16,150			5,655

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16–105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received by October 4, 2004.