The burden estimate was calculated as the time it takes to ''submit'' the protocol which consists of filling out the form and pressing the ''insert submission'' button, adding the password and pressing the ''mail to'' button, since the burden for protocol is already estimated under OMB control number 0910–0119 for nonclinical laboratory studies and OMB control number 0910–0346 for efficacy studies. The number of approved sponsors is 190, we routinely receive about 100 protocols a year, and the 12 minutes (.2 *60 minutes/hour) is an estimate based on talking to participating sponsors and our testing the use of the form.

Dated: October 16, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–26963 Filed 10–24–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–1146]

Guidance for Industry: Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance (#152) entitled ''Guidance for Industry: Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern.'' This guidance document discusses a recommended approach for assessing the safety of antimicrobial new animal drugs with regard to their microbiological effects on bacteria of human health concern.

DATES: Submit written or electronic comments on agency guidances at any time.

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

Submit written requests for single copies of the guidance document 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.

FOR FURTHER INFORMATION CONTACT: Jeffrey M. Gilbert, Center for Veterinary Medicine (HFV–157), 7500 Standish Pl., Rockville, MD 20855, 301–827–0233, e-mail: *jgilbert@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 13, 2002 (67 FR 58058), FDA published a notice of availability for a draft guidance entitled ''Guidance for Industry: Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern'' giving interested persons until November 27, 2002, to submit comments. FDA considered all comments received and, where appropriate, incorporated them into the guidance.

This document provides guidance for industry on a possible process for evaluating the potential effects of antimicrobial new animal drugs on non-target bacteria as part of the new animal drug application process. This guidance document outlines a risk assessment approach for evaluating the microbial food safety of antimicrobial new animal drugs. Alternative processes that may be more appropriate to a sponsor's drug and its intended conditions of use, may be used to characterize the microbial food safety of that drug. FDA's purpose in this guidance is to ensure the safety of animal drugs used in food-producing animals and to evaluate the human health impact of their intended use.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115). The guidance represents the agency's current thinking about the safety of new animal drugs, with regard to their microbiological effects on bacteria of human health concern. The document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

FDA is announcing that a collection of information entitled ''Guidance for Industry: Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. In the **Federal Register** of September 19, 2003 (68 FR 54906), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. According to the Paperwork Reduction Act of 1995, a collection of information should display a valid OMB control number. The valid OMB control number for this information collection is 0910–0522 (expires April 30, 2005). A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

IV. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to this guidance. FDA periodically will review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the final guidance at any time. 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

Persons with access to the Internet may obtain a copy of the guidance document entitled ''Guidance for Industry: Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern'' from the Center for Veterinary Medicine home page at *http://www.fda.gov/cvm*.

Dated: October 6, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–27113 Filed 10–23–03; 12:30 pm]

BILLING CODE 4160–01–S