FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under 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(c) 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, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing 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.

Substantial Evidence of Effectiveness of New Animal Drugs—21 CFR Part 514 (OMB Control Number 0910–0356)—Extension

Description: Congress enacted the Animal Drug Availability Act of 1996 (ADAA) (Public Law 104–250) on October 9, 1996. As directed by the ADAA, FDA published a regulation, § 514.4(a) (21 CFR 514.4(a)), to further define substantial evidence in a manner that encourages the submission of NADA's and supplemental NADA's and encourages dose range labeling. Under the ADAA, substantial evidence is the standard that a sponsor must meet to demonstrate the effectiveness of a new animal drug for its intended use under the conditions suggested in its proposed labeling. Section 514.4(a) gives FDA greater flexibility to make case-specific scientific determinations regarding the number and types of adequate and well-controlled studies that will provide, in an efficient manner, substantial evidence that a new animal drug is effective. FDA believes this regulation will address the following issues: (1) Reduce the number of adequate and well-controlled studies necessary to demonstrate the effectiveness of certain combination new animal drugs; (2) eliminate the need for an adequate and well-controlled dose titration study; and may, in limited instances, (3) reduce or eliminate the number of adequate and well-controlled field investigations necessary to demonstrate by substantial evidence the effectiveness of a new animal drug. Table 1 of this document represents the estimated burden of meeting the substantial evidence standard.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
514.4(a)	190	4.5	860	632.6	544,036

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

Dated: September 15, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–23940 Filed 9–18–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–1146]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concerns

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by October 20, 2003.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974, or e-mail comments to *Fumie_Yokota@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 4B–41, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concerns

This guidance document discusses a recommended approach for assessing the antimicrobial resistance concerns as part of the overall preapproval safety evaluation of new animal drugs, focusing on the microbiological effects on bacteria of human health concern. In particular, the guidance describes a methodology sponsors of antimicrobial new animal drug applications for food-producing animals may use to complete a qualitative antimicrobial resistance risk assessment. This risk assessment

should be submitted to FDA for the purposes of evaluating the safety of the new animal drug to human health. The guidance document outlines a process for integrating relevant information into an overall estimate of risk and discusses possible risk management strategies.

Table 1 of this document represents the estimated burden of meeting the new reporting requests. The burden estimates for these information collection requests are based on information provided by the Office of New Animal Drug Evaluation, Center for Veterinary Medicine. The guidance document describes the type of information that should be collected by the drug sponsor when completing the antimicrobial resistance risk assessment. FDA will use the risk assessment and supporting information to evaluate the safety of original (21 CFR 514.1) or supplemental (21 CFR 514.8) new animal drug applications (NADAs) for antimicrobial drugs intended for use in food-producing animals.

In the **Federal Register** of September 13, 2002 (67 FR 58058), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received in response to that notice.

FDA estimates the burden for this collection of information:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section 514.1(b)(8) and 514.8(a)(2)	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Hazard Identification (initial scoping of issues--relevant bacteria, resistance determinants, food products; preliminary data gathering)	5	1	5	30	150
Release Assessment (literature review; review of research reports; data development; compilation, and presentation)	5	1	5	1,000	5,000
Exposure Assessment (identifying and extracting consumption data; estimating probability of contamination on food product)	5	1	5	8	40
Consequence Assessment (review ranking of human drug importance table)	5	1	5	4	20
Risk Estimation (integration of risk components; development of potential arguments as basis for overall risk estimate)	5	1	5	12	60
Risk Management (discussion of appropriate risk management activities)	5	1	5	30	150
Total Burden					5,420

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]FDA estimates that on an annual basis an average of five NADAs (including original applications and major supplements) would be subject to information collection under this guidance. This estimate is based on a review of the number of major NADA approvals that occurred between October 1997 and October 2001. During that 4-year period, an average of five antimicrobial NADAs (including original and major supplements) was approved in food-producing animals per year. This estimate excludes NADAs for antimicrobial drug combinations, generic drug applications (abbreviated new animal drug applications), and certain supplemental NADAs.

Dated: September 15, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–23941 Filed 9–18–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0124]

Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion'' dated September 2003. The guidance document provides recommendations to blood collection and transfusion facilities on reporting fatalities related to human blood and blood component collection or transfusion to FDA's Center for Biologics Evaluation and Research (CBER). The guidance announced in this notice finalizes the draft guidance of the same title dated June 2002.

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