meeting. Limited space is available, and early registration is encouraged. Registration forms are available on the Dockets Management Branch Web site at www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm

If you need special accommodations for a disability, please contact the DoubleTree Hotel at least 7 days in advance of the meeting.

Meeting Agenda: The meeting will consist of a series of oral presentations in the morning to explain the content of the draft guidance document. The agenda in the afternoon will consist primarily of sessions to address specific questions and to provide opportunity for public comment. The meeting agenda will be made available on the CVM Web site at www.fda.gov/cvm/antimicrobial/ar_meetings.htm.

Transcripts: You may request a transcript of the meeting in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857. The transcript of the public meeting will be after the meeting, at a cost of 10 cents per page. You may also examine the transcript of the meeting at the Dockets Management Branch (see *Comments and Electronic Access*) between 9 a.m. and 4 p.m., Monday through Friday and on the CVM Web site at www.fda.gov/cvm/antimicrobial/ar_meetings.htm.

SUPPLEMENTARY INFORMATION:

Background

In January 1999, FDA announced the availability of a discussion document entitled ''Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (framework document) (64 FR 887, January 6, 1999). The framework document laid out possible strategies for managing the potential risks associated with use of antimicrobial drugs in food-producing animals.

The current draft guidance document outlines an approach for implementing concepts described in the Framework Document. The draft document provides guidance on a risk analysis process as a possible means for evaluating antimicrobial resistance concerns as part of the preapproval safety evaluation of a new animal drug. The new animal drug sponsor may use this guidance and the methodology described to conduct a qualitative risk assessment to help evaluate antimicrobial resistance concerns as part of an overall preapproval safety evaluation of their proposed animal drug product. If the sponsor elects to use this process, the qualitative antimicrobial resistance risk assessment and supporting data should be submitted to FDA for review. FDA's purpose in this guidance is to ensure that antimicrobial new animal drugs intended for use in food-producing animals are safe with regard to human health.

Also in this issue of the **Federal Register**, FDA is publishing the notice of availability of the guidance document entitled ''Draft Guidance for Industry: Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern.''

Dated: September 9, 2002.

Margaret M. Dotzel

Associate Commissioner for Policy.

[FR Doc. 02–23386 Filed 9–10–02; 4:37 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1146]

''Draft 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 is announcing the availability of a draft guidance document (# 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 draft 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 guidance by November 27, 2002 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 requirements must be received by November 12, 2002.

ADDRESSES: Submit written requests for single copies of the draft 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.

Submit written comments on the draft guidance document to the Dockets Management Branch (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 draft guidance document and the docket number found in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the collection of information requirements to the Dockets Management Branch (see previous paragraph). Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV–2), 7519 Standish Pl., Rockville, MD 20855, 301–827–4514, e-mail: wflynn@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Antimicrobial drugs have been used since the mid-20th century to control and cure infectious diseases in humans. Since their discovery, these drugs have prevented millions of deaths worldwide by killing harmful bacteria or inhibiting their growth. Since the 1950s, when their use in animal production became widespread, antimicrobial drugs have helped to ensure animal health and have helped to provide an abundant and affordable supply of meat, milk, and eggs.

However, soon after antimicrobial drugs became widely used, scientists noted the phenomenon of antimicrobial resistance. Use of antimicrobial drugs leads to antimicrobial resistance because, when an antimicrobial drug is used to treat an infection, the bacteria most sensitive to the drug die or their growth is inhibited. Those bacteria that have, or acquire, the ability to resist the antimicrobial drug survive and eventually replace the more drug-sensitive bacteria.

Additionally, bacteria can become resistant indirectly when resistance traits are passed from other bacteria by mechanisms that allow the exchange of their genetic material. In this way, resistance can be transferred from nonpathogenic bacteria to bacteria that are pathogenic to humans.

In recent years, national and international health organizations have considered evidence that use of antimicrobial drugs in food-producing animals could lead to the emergence of antimicrobial drug-resistant bacteria that are pathogenic to humans. For instance, *Salmonella* and *Campylobacter* can exist in the digestive tract of food-producing animals without causing illness, but these same bacteria, when ingested by humans eating meat, milk, or eggs, can cause severe food-borne illness. FDA's main concern is that use of antimicrobial drugs in food-producing animals may lead to the emergence of bacterial pathogens that are resistant to drugs used to treat human illness, potentially making human illnesses more difficult to treat.

Since the 1970s, FDA has evaluated the effects of antimicrobial drug products on enteric bacteria of food-producing animals in determining whether certain feed uses of an antimicrobial drug are safe under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b). FDA also published in the **Federal Register** of December 17, 1999 (64 FR 70715), a final guidance entitled ''Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals (Guidance # 78). This guidance stated FDA's intention to consider the potential human health impact of the microbiological effects associated with all uses of all classes of antimicrobial new animal drugs intended for use in food-producing animals. Guidance # 78 discussed the impact of antimicrobial drug use on the rate and extent of resistance emergence and on the quantity of bacteria in animals that are pathogenic to humans.

In January 1999, FDA announced the availability of a discussion document entitled ''Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (framework document) (64 FR 887, January 6, 1999). The framework document laid out possible strategies for managing the potential risks associated with use of antimicrobial drugs in food-producing animals.

The current draft guidance document outlines a risk analysis methodology as a process for evaluating antimicrobial resistance concerns as part of the pre-approval safety evaluation of a new animal drug. If the new animal drug sponsor elects to use this risk analysis methodology, it may use this guidance and the methodology described to conduct a qualitative risk assessment to help evaluate antimicrobial resistance concerns as part of an overall preapproval safety evaluation of their proposed animal drug product. The sponsor of the new animal drug electing to use this methodology should complete the qualitative antimicrobial risk assessment and submit it to FDA for review. The antimicrobial risk assessment is intended to characterize the human health risk associated with the proposed use of a given antimicrobial drug in animals. 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 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft 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

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: (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.

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

This draft 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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR 514.1(b)(8) and 514.8(a)(2)	No. of Respondents	Annual Frequency of Response	Total Annual Responses[1]	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 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) were approved in food-producing animals per year. This estimate excludes NADAs for antimicrobial drug combinations, generic drug applications (ANADAs), and certain supplemental NADAs.

IV. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written comments regarding this draft guidance document. Submit written comments by [see **DATES**] to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Written comments concerning the information collection requirements must be received to the Dockets Management Branch by see (**DATES**). A copy of the document and received comments are available for public examination in the Documents Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Also in this issue of the **Federal Register**, FDA is publishing a notice of meeting to discuss this guidance.

V. Electronic Access

Electronic comments may be submitted on the Internet at http://www/fda/gov/dockets/ecomments. Once on this Internet site, select 98D–1146 ''Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern'' and follow the directions. A copy of this document may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm.

Dated: September 9, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–23387 Filed 9–10–02; 4:37 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications