correct numbers (AIDS or STD) and Symposium software which can assist the hotlines in several areas, including quickly (1) determining what happened to a call that may be in the queue, (2) compiling a geographic distribution table of all calls throughout the United States, including ages of callers, and (3) routing calls to the English, Spanish or TTY service.

For the AIDS and STD integrated English service, the estimated number of persons surveyed for the active survey is 34,520, and the average active survey length is 72 seconds with a yearly burden of 691 hours. It is estimated that passive surveys are completed on 29,420 calls, and the average passive survey length for completion is 179 seconds, with a yearly burden of 1,463 hours.

Active surveys for the Spanish service for the AIDS Hotline are estimated to be about 5,040 calls with an average active survey length of 88 seconds. The average number of passive surveys estimated for the Spanish service is 5,000. All callers are surveyed from the TTY service and one out of three callers are surveyed from the Spanish service.

The special events survey will be used to provide information for special promotional campaigns for HIV/AIDS and STDs. The campaigns will generally include the hotline number in any public service announcements (PSAs), advertisements, or tag lines for television shows. On occasion, specific questions will be added to address the content of the special event or PSA. CDC anticipates that it conduct up to 5 special events in the next 3 years. The total estimated annualized burden for this data collection is 1,342 hours.

Survey	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
NAH (English)	21,760	1	1.5/60
NSTDH (English)	12,760	1	1.5/60
NAH (Spanish)	5,040	1	2/60
NSTDH (Spanish)	3,780	1	2/60
NAH (TTY)	200	1	7/60
NSTDH (TTY)	150	1	7/60
Customer Service (English)	150	1	1/60
Customer Service (Spanish)	60	1	7/60
Special Events:			
NAH (English)	2,700	1	2/60
NAH (Spanish)	300	1	2/60
NSTDH (English)	1,000	1	2/60
NSTDH (Spanish)	200	1	2/60

Dated: September 3, 2002.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 02–23285 Filed 9–12–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1146]

Discussion of ''Draft Guidance for Industry: Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern;'' Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following meeting: ''Discussion of Draft Guidance for Industry: Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern.'' The topic to be discussed is this draft guidance document that describes an approach for implementing concepts previously considered in the FDA framework document on antimicrobial resistance (64 FR 887, January 6, 1999). The draft guidance outlines a method for assessing the safety of antimicrobial new animal drugs intended for use in food-producing animals.

Date and Time: The public meeting will be held on Wednesday, October 2, 2002, from 9 a.m. to 5 p.m. Interested persons, who wish their comments to be considered during the meeting, may submit written or electronic comments by September 25, 2002, to the Dockets Management Branch (see *Comments and Electronic Access*).

Location: The meeting will be held at the DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD, 20852, 301–468–1100.

Comments and Electronic Access. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of written comments are to be submitted, except that individuals may submit one copy. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the full title and Docket No. 98D–1146 found in brackets in the heading of this document. A copy of the received comments is available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Oral comments regarding the draft guidance may be provided during the public comment sessions. Since time for public comments is limited, prior notification of your intent to comment is encouraged. Please register and submit a short summary of your comments by September 25, 2002; faxed copies of comments are permissible. We encourage consolidation of like-minded presentations to provide sufficient opportunity for public comment.

For General Information Contact: Aleta Sindelar, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4515; FAX 301–827–4335 or e-mail: asindela@cvm.fda.gov.

For Information About Registration/Oral Comments Contact: Anna Roy, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–2947; FAX 301–827–4335 or e-mail: aroy@cvm.fda.gov.

Registration: Registration is required. There is no registration fee for the

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.