Twinbrook Metro Station located several blocks west of the meeting location.

Interested persons may submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written comments on the use of XML to create a cumulative table of contents. 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. Comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 22, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–33370 Filed 12–28–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1677]

Discussion Paper: An Approach for Establishing Thresholds in Association With the Use of Antimicrobial Drugs in Food-Producing Animals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a discussion paper entitled ''An Approach for Establishing Thresholds in Association With the Use of Antimicrobial Drugs in Food-Producing Animals (discussion paper).'' This discussion paper reflects the Center for Veterinary Medicine's (CVM's) current thinking on one concept for establishing resistance thresholds for antimicrobial drugs used in food-producing animals. The concept will be presented for discussion at a public meeting on January 22 to 24, 2001. CVM wants to receive comment on scientific and policy issues regarding this concept, as well as suggestions for alternative approaches.

DATES: Submit written comments on this discussion paper by April 9, 2001.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

See the **SUPPLEMENTARY INFORMATION** section for electronic access to the discussion paper. Persons without Internet access may submit written requests for single copies of this discussion paper to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: *For general inquiries:* Sharon R. Thompson, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4514, e-mail at sthompso@cvm.fda.gov.

For technical inquiries: William T. Flynn, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7570, e-mail at wflynn@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 6, 1999 (64 FR 887), FDA announced the availability of a discussion paper entitled ''A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial Drugs Intended for Use in Food-Producing Animals'' (the Framework Document). FDA made the Framework Document available to the public to initiate discussions with the scientific community and other interested parties on the agency's thinking about appropriate underlying concepts to be used to develop new policy for evaluating and ensuring that antimicrobial drug use in food-producing animals is safe for the public health. The Framework Document discussed several strategies for addressing concerns regarding the development of antimicrobial drug resistance associated with the use of antimicrobial drugs in food-producing animals. These strategies covered both preapproval and postapproval approaches and included: (1) Revision of the preapproval safety assessment for antimicrobial resistance for new animal drug applications to consider all uses of antimicrobial drugs in food-producing animals, (2) categorization of antimicrobial drugs based upon the importance of the drug for human medicine and upon which preapproval and postapproval requirements would be based, (3) postapproval monitoring of the development of antimicrobial drug resistance, and (4) elaboration of resistance and monitoring thresholds.

The Framework Document discussed the concept of two thresholds, the resistance threshold and the monitoring threshold, that would be established prior to the approval of an antimicrobial new animal drug for use in food-producing animals to ensure that food products derived from the animal species treated with the drug are safe for consumers. The resistance threshold would be established in humans to represent the upper limit of resistant bacteria that can be transferred from animals to consumers. The Framework Document discussed the possibility of establishing resistance thresholds based on human data, animal data, or both.

The Framework Document noted that monitoring thresholds also would be established to guide the postapproval monitoring of resistance development in animals. According to the Framework Document, a monitoring threshold would need to be determined for each antimicrobial drug prior to approval, and the threshold could vary depending on the human or animal pathogen of concern. Monitoring thresholds would be established in animals so that they would serve as an early warning system, signaling when loss of susceptibility or resistance prevalence is approaching the resistance threshold.

If a monitoring threshold were reached, the drug sponsor could implement mitigation actions to address the loss of susceptibility or the increasing resistance trend. According to the concepts described in the Framework Document, if mitigation actions were found to be unsuccessful, and resistance levels exceeded the resistance threshold, withdrawal of the approval of the drug for the use(s) of concern would be warranted.

The discussion paper, which is the subject of this notice of availability, further describes an approach for establishing thresholds intended to limit the emergence and spread of antimicrobial resistance in human pathogens attributed to antimicrobial drug use in food-producing animals. The discussion paper attempts to describe the possible complexities of this approach to establishing thresholds in order to encourage discussion before, during, and after the January public meeting mentioned above. A notice of the public meeting was announced in the **Federal Register** of September 26, 2000 (65 FR 57820).

The discussion paper discusses the use of two types of thresholds, a human health threshold and a resistance-in-animals threshold. The human health threshold represents the level at which there is no longer a reasonable certainty of no harm to human health associated

with antimicrobial resistance development as a consequence of antimicrobial drug use in food-producing animals. The resistance-in-animals threshold represents the upper limit of acceptable levels of antimicrobial resistance in a food-producing animal species. This resistance threshold is derived through a risk assessment model that builds a link between the human health threshold and the resistance levels in animals. Therefore, exceeding the resistance threshold would be considered an unacceptable human health risk.

II. Comments

This discussion paper is being distributed at this time for consideration by the public in anticipation of the January 22 to 24, 2001, public meeting. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this discussion paper by April 9, 2001. Two copies of any comments are to be submitted, except that an individual may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the docket including transcript and comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of the discussion paper may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm/.

Dated: December 21, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–33215 Filed 12–26–00; 11:47 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for the opportunity for public comment on proposed data collection projects (section 3506 (c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is 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: Ryan White CARE Act: Cross-Title Data Report Form (CTDR)—New

The Cross Title Data Report (CTDR) form, created in 1999 by the HIV/AIDS Bureau of the Health Resources Services Administration (HRSA), is designed to collect information from grantees, as well as their subcontracted service providers, funded under Titles I, II, III and IV of the Ryan White Comprehensive AIDS Emergency (CARE) Act of 1990, as amended by the Ryan White CARE Act Amendments of 1996 and 2000 (codified under Title XXVII of the Public Health Services Act). The purpose of the Ryan White CARE Act is to provide emergency assistance to localities that are disproportionately affected by the human immunodeficiency virus (HIV) epidemic and to make financial assistance available for the development, organization, coordination, and operation of more effective and cost-efficient systems for the delivery of essential services to persons with HIV disease. The CARE Act also provides grants to states, eligible metropolitan areas, community-based programs, and early intervention programs for the delivery of services to individuals and families with HIV infection. All Titles of the CARE Act specify HRSA's responsibilities in the administration of grant funds, the allocation of funds, the evaluation of programs for the population served, and the improvement of the quantity and quality of care. Accurate records of the providers receiving CARE Act funding, the services provided, and the clients served continue to be critical to the implementation of the legislation and thus are necessary for HRSA to fulfill its responsibilities.

Previously, grantees under each Ryan White CARE Act Title reported aggregate data on distinct Title-specific forms. The CTDR, an aggregate of these data collection forms, is designed to reduce the reporting burden for grantees with concurrent reporting responsibilities, and to eliminate title-specific reporting in order to reduce duplication among grantees and providers funded through multiple CARE Act Titles. The CTDR form collects data from grantees and their subcontracted service providers on six different areas: service provider information, client information, services provided/clients served, demographic information, AIDS Pharmaceutical Assistance and AIDS Drug Assistance Program, and the Health Insurance Program. Collected on an annual basis, the primary purposes of the CTDR are to: (1) Characterize the organizations from which clients receive services; (2) provide information on the number and characteristics of clients who receive CARE Act services; and (3) enable HAB to describe the type and amount of services a client receives. In addition to meeting the goal of accountability to Congress, clients, advocacy groups, and the general public, information collected on the CTDR is critical for HRSA, state and local grantees, and individual providers to assess the status of existing HIV-related service delivery systems.

The estimated response burden for CARE Act grantees is estimated as:

Title under which grantee is funded	Number of grantees respondents	Responses per grantee	Hours to coordinate receipt of data reports from providers	Total hour burden
Title I only	54	107	40	2,160