rules and regulations for advisory committee proceedings except as otherwise determined by the Commissioner or designee. Similarly, interactions between and among the ''parent'' Committee and the four Subcommittees, will be in accordance with rules and regulations for advisory committee proceedings established requirements. The Subcommittee's findings, conclusions, and recommendations will be reported to the ''parent'' Committee. As a general matter, included in this report will be a recommendation from the Subcommittee on final disposition of the assigned topic. Generally, matters that cut across the agency program areas would fall under the purview of the ''parent'' Committee. As a general rule, issues relating to the microbiological safety of food will be addressed by the National Advisory Committee on Microbiological Criteria for Foods.

Criteria for Members

Persons nominated for membership on the Committee shall be knowledgeable in the fields of physical sciences, biological and life sciences, food science, risk assessment and other relevant scientific and technical disciplines. The agency is particularly interested in considering candidates with a comprehensive background in food technology, molecular biology, genetics, biotechnology, and a variety of medical specialties, as many issues brought before the Committee involve medical or epidemiologic impact on nutrients, additives, contaminants, or other constituents of the diet, such as dietary supplements. The term of office is up to 4 years.

The Committee includes technically qualified members who are identified with consumer interests and representatives of industry interests.

Nomination Procedures

Interested persons may nominate one or more qualified persons for membership on the Committee. Nominations shall state that the nominee is willing to serve as a member of the Committee and appears to have no conflict of interest that would preclude Committee membership. Additionally, the nominee's mailing address, telephone number, and curriculum vitae must accompany the nomination. The agency cannot guarantee further consideration of nominations that do not include this requested information. Potential candidates will be asked by FDA to provide detailed information concerning such matters as financial holdings, employment, consultancies, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

Industry Representatives

Regarding nominations for members representing industry interests, a letter will be sent to each person or organization that has made a nomination and to other organizations that have expressed an interest in participating in the selection process together with a complete list of all such organizations and the nominees. The letter will state that it is the responsibility of each nominator or organization that has expressed an interest in participating in the selection process to consult with the others to provide a consensus slate of possible members representing industry interests within 60 days. In the event that a slate of nominees has not been provided within 60 days, the agency will select an industry representative for each such vacancy from the entire list of industry nominees to avoid delay or disruption of the work of the Committee. The agency is particularly interested in nominees that possess the essential scientific credentials needed to participate fully and knowledgeably in the Committee's deliberations. In addition to this expertise, the agency believes that it would be an advantage to the Committee's work if the individual(s) had special insight and direct experience into specific industrywide issues, practices, and concerns that might not otherwise be available to others not similarly situated.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: July 21, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–19096 Filed 7–27–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0969]

Establishment of Resistance and Monitoring Thresholds in Food-Producing Animals; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following meeting: Public Meeting Regarding the Establishment of Resistance and Monitoring Thresholds in Food-Producing Animals. The topic to be discussed is the Center for Veterinary Medicine's (CVM's) current thinking on concepts for the establishment of resistance and monitoring thresholds in food-producing animals. CVM will seek scientific input from experts at this meeting on these concepts as well as suggestions for alternative approaches.

Date and Time: The meeting will be held on October 10 and 11, 2000, 8:30 a.m. to 5 p.m. Written comments may be submitted until December 11, 2000.

Addresses: The meeting will be held at The DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD 20852. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

For general inquiries about the meeting and registration contact: Lynda W. Cowatch, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5281, FAX: 301–594–2298.

For technical inquiries contact: Aleta Sindelar, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0148.

Registration: Registration is required. There is no registration fee for the meeting. Limited space is available, and early registration is encouraged. Logistics for the meeting and the registration form are available on the Internet at http://www.fda.gov/cvm/fda/mappgs/registration.html. Please send the registration form to Lynda Cowatch (address above). Additional information about the meeting and the agenda will be available on the Internet (Internet site above) before the meeting.

If you need special accommodations due to a disability, please contact the DoubleTree Hotel at least 7 days in advance, 800–222–8733.

Transcripts: Transcripts of the meeting will be available on the Internet at http://www.fda.gov/cvm.

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 New Animal 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 microbial safety policies protective of the public health. This document discussed several risk management approaches to the regulatory management of antimicrobial drug resistance associated with food-producing animal use of antimicrobials. 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 assess all uses for microbial safety, (2) categorization of antimicrobials based upon the importance of the drug for human medicine and upon which pre- 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 treated animals 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.

Monitoring thresholds would also 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 prior to approval, and the threshold may 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 would implement mitigation actions to address the loss of susceptibility or increasing resistance trend. If mitigation were not successful, and resistance continued to increase and reach the resistance threshold, withdrawal of the approval of the drug for the use(s) of concern would be warranted.

II. Submission of Comments

Interested persons may submit written comments regarding this meeting until December 11, 2000. Written comments should be submitted to the Dockets Management Branch (address above), or by fax to 301–827–6870. Comments should be identified with the docket number found in the brackets in the heading of this document.

III. Related Information

Transcripts of the three previous CVM public meetings on antimicrobial resistance, related public comments, the ''Draft Risk Assessment on the Human Health Impact of Fluoroquinolone Resistant Campylobacter Associated with the Consumption of Chicken (Revised as of February 9, 2000),'' and ''A 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'' can be found on the Internet at http://www.fda.gov/cvm/fda/mappgs/antitoc.html.

Dated: July 20, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–19048 Filed 7–27–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0495]

Prescription Drug User Fee Act (PDUFA) II Five-Year Plan—FY 2000 Update; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an internal planning document entitled ''PDUFA II Five-Year Plan: FY 2000 Update.'' The updated plan to achieve PDUFA II goals for the drug review process takes into account changes in revenue projections and workload based on actual revenue and application receipts in fiscal year (FY) 1998 and FY 1999 and updated projections for FY 2000 through FY 2002.

DATES: Submit written comments on the plan at any time. Comments will be considered as the agency makes annual adjustments to the plan in the second quarter of each FY.

ADDRESSES: Copies of this document are available on the Internet at www.fda.gov/oc/pdufa2/5yrplan.html. For those without Internet access, single copies of this plan may be obtained from the Office of Management and Systems (HF–20), Attention: Frank P. Claunts (HF–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please send a self-addressed adhesive label to assist that office in processing your request.

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

FOR FURTHER INFORMATION CONTACT: Frank P. Claunts, Office of Management Systems (HF–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4427.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of an internal planning document entitled ''PDUFA II Five-Year Plan—FY 2000 Update.'' PDUFA was amended and extended through the year 2002 by the Food and Drug Administration Modernization Act of 1997. The amended and extended PDUFA is referred to as PDUFA II. PDUFA II authorizes appropriations and fees that will provide FDA with resources to sustain the drug review staff developed through FY 1997 and to achieve the even more stringent new goals.

The FY 2000 updated plan begins with a statement of purpose, provides background information on PDUFA and a summary of the new goals, and updates the 10 major assumptions on which the plan is based. This is the second update of the plan since it was initially published in July 1998. The updated plan summarizes individual plans of agency components with major PDUFA responsibilities, and it also provides a consolidated agency summary. The updated plan to achieve PDUFA II goals for the drug review process takes into account changes in revenue projections and workload based on actual revenue and application receipts in FY 1998 and FY 1999 and updated projections for FY 2000 through FY 2002. Attachments include: The **Federal Register** notice of December 28, 1999 (64 FR 72669) establishing prescription drug user fee rates for FY 2000, updated 5-year estimates of PDUFA fees and revenues, and the revised PDUFA II Information Management Five-Year Plan.

We are making this plan available to all who have an interest. We welcome comments and will consider them in the future as annual adjustments are made to the plan.