Location: The public workshop will be held at the University of Maryland, Stamp Student Union Building ''Atrium,'' College Park, MD.

Contact: June A. Bradlaw, Center for Food Safety and Applied Nutrition (HFS–508), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 301–594–5883, FAX 301–594–0517.

Registration: Send registration information (name, title, firm name, address, telephone and fax numbers) to Jacqueline M. Williams, Center for Food Safety and Applied Nutrition (HFS–315), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4224, FAX 202–205–4422. Registration should be sent by August 3, 1998, or register on-line at ''http://www.foodsafety.gov/~mow/jifsan.html''. There is no registration fee for this workshop.

If you need special accommodations due to a disability contact June A. Bradlaw at least 7 days in advance.

SUPPLEMENTARY INFORMATION: On January 25, 1997, the President announced the National Food Safety Initiative. As a part of this initiative, a need was recognized for the development of methods and models for enhanced food safety risk assessment, particularly for microbiological pathogens and their toxins.

Risk assessment generally characterizes the nature and magnitude of the risks associated with hazards to human health, and helps to clarify the assumptions and degree of scientific certainty of the data associated with risk estimates. Risk assessments require specific information on the hazard and on the exposed populations to provide meaningful information to public health officials to develop and arrive at risk-management decisions. Although risk assessment methods are fairly well established for evaluating chemicals and contaminants in food, risk assessment is far less developed for foodborne pathogens. The May 1997 National Food Safety report to the President noted that an intensive commitment is necessary to fill this gap and develop critically needed methods for analyzing food safety data and addressing its uncertainty.

A component of this effort has been the establishment of a joint Risk Assessment Consortium of Federal agencies with food safety risk-management responsibilities. The role of the consortium is: To advance the science of microbial food safety risk assessment; to serve as advisors for direction and review of Risk Assessment Clearinghouse activities; and to assist agencies in fulfilling their specific food safety regulatory mandates. Consistent with these goals, JIFSAN will host an open workshop that will explore issues requisite to quantifying the risk of illness associated with foodborne pathogenic microorganisms. Guidance in the development of this workshop has been provided by the Risk Assessment Consortium.

JIFSAN is a multi-disciplinary research and education program established by FDA and the University of Maryland in 1996. JIFSAN is a major component of the FDA's integration with academic institutions to create intellectual partnerships. JIFSAN includes research and outreach components from the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), and the University of Maryland. JIFSAN combines resources from FDA, the primary Federal public health agency responsible for the safety of the nation's food supply, an established research university, and public and private partnerships to provide the scientific basis for assuring a safe, wholesome food supply. JIFSAN provides a neutral environment in which experts from industry, consumer and trade groups, international organizations, government, and academia can pool their resources and ideas to provide the scientific base for the development of sound public health policy.

The goal of this workshop is to evaluate the current state of science for quantifying dose-response relations for foodborne pathogens and to identify opportunities and alternative sources of information that can be used to develop enhanced dose-response models for conducting microbial risk assessments. Broad areas to be discussed will include: (1) Current modeling of foodborne pathogenic microorganisms, (2) how traditional dose-response models can be adapted to provide better estimates of the severity and likelihood of illness due to foodborne pathogens, and (3) alternative approaches and sources of information for elucidating dose-response relations.

Speakers will consider scientific principles and methods that can be used or adapted to elucidate dose-response relations for microorganisms that are pathogenic in humans. This will include detailed discussion concerning how these relations can be modeled for use in microbial risk assessment. Discussions will focus on how these data, which are often developed for other purposes, can be useful for dose-response models. Emphasis will be placed on modeling susceptible populations, use of animal models and improvement of methods of data collection.

The draft scientific agenda includes the following presentations: Classical and Modern Chemical Dose-Response Models–Concepts and Applications in Risk Assessment; Limitations of Current Dose-Response Models for use in Modeling Dose-Response for Pathogenic Microorganisms; Linking In Vitro, Animal and Human Studies Through Mechanisms of Pathogenesis; Correlating Host Resistance and Susceptibility With Biomarkers From In Vitro, Ex Vivo and Animal Models; Use of Epidemiological Data in Dose-Response Models; Estimation of Infective Dose Based on an Actual Outbreak Investigation; and Suitability of Small Human Clinical Studies to Measure Pathogenesis of Foodborne Pathogens. The agenda also includes open discussion periods during which participants will be encouraged to discuss the merits of different approaches for developing microbial risk assessment dose-response models and to identify additional approaches not identified in the formal presentations.

The workshop will serve as an initial foray into issues and questions surrounding the relationship between the numbers of pathogenic microorganisms consumed and the resultant illness. The workshop is intended to facilitate a scientific discussion that will serve as a basis for further dialogue with the greater scientific community in structuring approaches to dose-response modeling of foodborne pathogens.

The program agenda and workshop abstracts will be posted on the world wide web (WWW) at ''http://www.foodsafety.gov/~mow/jifsan.html''. Verbatim transcripts will also be posted on the WWW after the workshop.

Dated: July 24, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20299 Filed 7–24–98; 4:44 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0548]

Draft Guidances for Industry on the Development of Antimicrobial Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Office of Drug Evaluation IV (ODE IV), Center for Drug Evaluation and Research (CDER), is announcing the availability of several draft guidance documents on the development of antimicrobial drug products. A general draft guidance document entitled ''Developing Antimicrobial Drugs—General Considerations for Clinical Trials'' discusses issues common to the development of all antimicrobial drugs. The companion draft guidance documents address issues related to developing drugs to treat individual indications. These draft guidance documents are intended to help sponsors design clinical trials that will yield information the agency can use to determine whether the antimicrobial drug under study is safe and effective in the treatment of the specific infection studied. Key elements of these draft guidance documents will be discussed at a July 29, 30, and 31, 1998, Anti–Infective Drugs Advisory Committee meeting.

DATES: Written comments on the draft guidance documents may be submitted by October 27, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance documents are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance documents to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance documents to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Renata Albrecht, Center for Drug Evaluation and Research (HFD–590), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2336.

SUPPLEMENTARY INFORMATION: FDA's divisions of Anti–Infective Drug Products, Special Pathogens and Immunologic Drug Products, and Anti–Viral Drug Products in CDER's ODE IV are issuing the first documents in a series of draft guidance documents that are intended to assist sponsors in designing, carrying out, and analyzing the results of clinical trials for the development of antimicrobial drug products. A general draft guidance document entitled ''Developing Antimicrobial Drugs—General Considerations for Clinical Trials'' discusses issues common to all antimicrobial drugs. The companion draft guidance documents address issues related to developing drugs to treat individual indications. Key elements from these draft guidance documents and related issues will be discussed at an Anti–Infective Drugs Advisory Committee meeting on July 29, 30, and 31, 1998 (63 FR 34655, June 25, 1998).

In the **Federal Register** of July 21, 1998 (63 FR 39096), ODE IV announced its plans for revising existing guidance documents and preparing new guidance documents on the development of antimicrobial drug products for the treatment of infections. ODE IV is reviewing, updating, consolidating, and revising its existing guidance documents and identifying topics for future guidance documents. In that notice, ODE IV explained its plan and requested public comment on topics for future guidance document development. The draft guidance documents are a part of ODE IV's guidance development plan.

The general draft guidance document being made available is entitled ''Developing Antimicrobial Drugs—General Considerations for Clinical Trials.'' The draft companion guidances are being made available on individual indications as follows:

- Uncomplicated urinary tract infections,
- Uncomplicated and complicated skin and skin structure infections,
- Community-acquired pneumonia,
- Nosocomial pneumonia,
- Acute bacterial exacerbation of chronic bronchitis,
- Secondary bacterial infection of acute bronchitis,
- Acute otitis media,
- Acute uncomplicated gonorrhea,
- Acute sinusitus,
- Complicated urinary tract infections and pyelonephritis,
- Bacterial prostatitis,
- Early Lyme disease,
- Empiric therapy of febrile neutropenia,
- Vulvovaginal candidiasis,
- Streptococcal pharyngitis and tonsillitis,
- Bacterial meningitis, and
- Bacterial vaginosis.

Additional guidances are under development.

The information in these draft guidance documents represents the agency's current thinking on developing antimicrobial drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance documents to the Dockets Management Branch (address above). 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. The draft guidance documents and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 23, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20239 Filed 7–28–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0448]

Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables.'' The guidance document provides information on the electrocution hazard posed by unprotected patient electrical connectors. This guidance is intended to help affected parties understand the steps needed to achieve compliance with the performance standard for electrode lead wires and patient cables.

DATES: Written comments concerning this guidance must be received by October 27, 1998.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the guidance entitled ''Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables'' to the Division of Small Manufacturers