

research programs in the Division of Emerging and Transfusion Transmitted Diseases, OBRR, Center for Biologics Evaluation and Research.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 24, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00-22463 Filed 8-29-00; 2:17 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Predicting Human Dose-Response Relationships From Multiple Biological Models: Issues With *Cryptosporidium Parvum*; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop sponsored by the interagency Risk Assessment Consortium (RAC) on the topic "Predicting human dose-response relationships from multiple biological models: Issues with *Cryptosporidium parvum*." The purpose of the workshop is to discuss the use of human and nonhuman models of infection and disease to predict human dose-response relationships for foodborne pathogens. The meeting will focus on research programs that are attempting to correlate dose-response data from human and nonhuman models, using the water- and food-borne parasite *C. parvum* as a sample organism. In the morning session, the meeting will also include a presentation, targeted to the public, on the role that dose-response modeling plays in setting food safety policy. The afternoon session will include a panelled technical discussion of both biological models and mathematical analysis (modeling) of biological data. In addition, an opportunity for public comment will be provided.

Date and Time: The meeting will be held on September 28, 2000, from 8:30 a.m. to 5 p.m.

Location: The meeting will be held at the Conference Center (rm. 1D00), United States Department of Agriculture (USDA) Center at Riverside, 4700 River Rd., Riverdale MD 20737-1238. Please see transportation information in the **SUPPLEMENTARY INFORMATION** section.

Contact: Lauren Posnick for Center for Food Safety and Applied Nutrition

(CFSAN) (HFS-308), FDA, 200 C St. SW., Washington, DC 20204, 202-205-4588, lposnick@cfsan.fda.gov, or Wesley Long, CFSAN (HFS-006), FDA, 200 C St. SW., Washington, DC 20204, 202-205-4024.

Registration: Preregistration is required by September 25, 2000. Walk-in registration is discouraged. Register online at www.foodriskclearinghouse.umd.edu. or send registration information (name, title, affiliation, address, e-mail address, telephone and fax numbers) to Shiho Sasamoto, CFSAN (HFS-006), 200 C St. SW., Washington, DC 20204, FAX 202-260-1654, 202-205-4355. If possible, please indicate whether you plan to drive and park your car in the Riverside lot. There is no registration fee. If you need special accommodations due to a disability, please contact Wesley Long at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Risk assessment generally characterizes the nature and magnitude of the risks associated with hazards to human health. A risk assessment provides an opportunity to organize scientific information and thus helps to clarify the necessary assumptions and degree of scientific certainty of the data used in the risk assessment. Risk assessments require specific information on the hazard and on the exposed populations to provide meaningful information to public health officials; this information may be considered in the development of risk-management decisions. Although risk assessment methods are fairly well established for evaluating chemicals in food, risk assessment for foodborne pathogens is far less developed. 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 RAC composed 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. In accordance with these goals, the RAC will host an open public meeting on dose-response relationships for human infections with the food- and waterborne parasite *C. parvum*.

The dose-response relationship for a foodborne pathogen describes the quantitative likelihood of humans

becoming infected or ill given exposure to a certain number (or dose) of pathogens. In general, researchers have proposed using both human clinical trials and nonhuman biological models as sources of data for establishing dose-response relationships. Both approaches are problematic: Human trials are complicated by ethical difficulties and both human trials and nonhuman biological models may not accurately represent real world dose-response relationships in humans. This meeting will review research programs that are attempting to estimate human dose-response relationships from human, animal, and in vitro models, focusing on *C. parvum* as a model organism. Speakers at the meeting will discuss the relative usefulness of different types of biological models for *C. parvum*, the potential for integrating data from different types of models, and the use of biological data to develop mathematical models of human dose-response relationships for *C. parvum* infections.

Specifically, the draft agenda includes presentations on the following topics: (1) Risk communication and dose-response modeling, including the importance of dose-response modeling to the scientist and the public, and the need for comprehensible dose-response models that can form the basis for public policy formulation; (2) parasite and host factors that affect the *Cryptosporidium*-human dose-response relationship, such as strain virulence, susceptible populations, and infection dynamics; (3) biological models of *Cryptosporidium* infection, including cell culture, animal, and human models; (4) the development and utility of mathematical models based on data from various biological models; and (5) a scientific panel discussion on such issues as: (a) The usefulness of biological models as a source of data for modeling human dose-response relationships, (b) the potential for integrating data from different biological models, (c) the adequacy of current models for modeling human dose-response relationships, and (d) the need to identify alternate models or data.

The meeting will also include a public comment period for general comments on *Cryptosporidium*, dose-response modeling, or other activities or issues related to risk assessment. For planning purposes, people who wish to speak during the public comment period must register in advance by contacting Wesley Long or Lauren Posnick (see *Contact* information above).

Parking at the USDA-Riverside Center is limited. Entry into the parking lot costs \$2 (exact change required). The

Riverside Center is located within walking distance (0.8 mile) of the College Park station on Metrorail's Green Line. There is also Metrobus service and free shuttle service from the College Park Metro station to the Riverdale Center. For more walking, Metro, and driving information/directions, see <http://www.aphis.usda.gov/biotech/direct.html> or <http://www.aphis.usda.gov/oa/aphismap.html>.

The program agenda will be posted on the Internet at www.foodriskclearinghouse.umd.edu. Following the workshop, a transcript of the meeting will be posted at the same site.

Dated: August 24, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-22230 Filed 8-30-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1434]

Guidance for Industry on Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System." The guidance provides recommendations to sponsors of investigational new drug applications (IND's), new drug applications (NDA's), abbreviated new drug applications (ANDA's), and supplements to these applications who wish to request a waiver of in vivo bioavailability (BA) and bioequivalence (BE) studies for immediate-release solid oral dosage forms.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for

single copies of this guidance 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 guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mei-Ling Chen, Center for Drug Evaluation and Research (HFD-350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5688.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled "Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System." This guidance provides recommendations on when in vivo BA/BE studies may be waived for IND's, NDA's, and ANDA's during either the pre- or postapproval period.

Although in vivo documentation of BA and BE has been required for many drug products, in some cases FDA has allowed the use of in vitro methods for documenting BA and BE. As noted both at 21 CFR 320.22, "Criteria for Waiver of Evidence of In Vivo Bioavailability or Bioequivalence," and at 21 CFR 320.24, "Types of Evidence to Establish Bioavailability or Bioequivalence," many options exist to allow demonstration of BA and BE through in vitro methods. This guidance describes recommendations for requesting waivers of in vivo BA/BE studies on the basis of the solubility and intestinal permeability of the drug substance and dissolution characteristics of the drug product, based on a biopharmaceutics classification system.

This Level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The guidance represents the agency's current thinking on the waiver of in vivo BA and BE studies for immediate-release solid oral dosage forms based on a biopharmaceutics classification system. 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 an approach satisfies the requirements of the applicable statutes, regulations, or both.

Interested persons may, at any time, submit written comments on the

guidance 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 guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 18, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00-22225 Filed 8-30-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-P-15A]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Medicare Current Beneficiary Survey (MCBS); Rounds 29-37;

Form No.: HCFA-P-15A (OMB# 0938-0568);

Use: The MCBS is a continuous, multipurpose survey of a nationally representative sample of aged and disabled persons enrolled in Medicare. The survey provides a comprehensive