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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 panel-led 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.

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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.

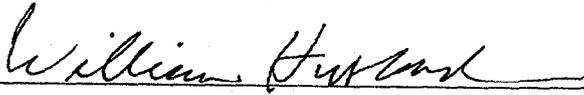
The meeting will also include a public comment period for general comments on *Cryptosporidium*, dose-response modeling, or other activities or issues related to risk assessment.

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.

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