

trials, which are often used in the evaluation of the safety and efficacy of a new antibacterial drug. The input from this public workshop will help in developing topics for further discussion.

Date and Time: The public workshop will be held on August 2, 2010, from 8:30 a.m. to 5:30 p.m. and on August 3, 2010, from 8 a.m. to 4 p.m.

Location: The public workshop will be held at the Crowne Plaza Hotel, 8777 Georgia Ave., Silver Spring, MD 20910. Seating is limited and available only on a first-come, first-served basis.

Contact Persons: Chris Moser or Lori Benner, Center for Drug Evaluation and Research, Food and Drug Administration, Office of Antimicrobial Products, 10903 New Hampshire Ave., Bldg. 22, rm. 6209, Silver Spring, MD 20993-0002, 301-796-1300.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early because space is limited. Seating will be available on a first-come, first-served basis. To register electronically, e-mail registration information (including name, title, firm name, address, telephone and fax numbers) to abtrialworkshop@fda.hhs.gov. Persons without access to the Internet can call Chris Moser or Lori Benner at 301-796-1300 to register (see *Contact Persons*). Persons needing a sign language interpreter or other special accommodations should notify Christine Moser or Lori Benner at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop regarding scientific issues in the design and conduct of clinical trials for antibacterial drug development.

Over the past decade, there have been public discussions on NI clinical trial design and the types of infectious disease indications for which the NI clinical trial design is appropriate. This public workshop will provide information on NI trial design, approaches to the justification of NI margins, and the assessment and timing of efficacy endpoints. Challenges in the conduct of clinical trials will be discussed, including good clinical practice and quality system approaches.

The workshop will include presentations and perspectives from FDA and from stakeholders involved in clinical research. The public workshop is intended to provide information for and gain perspective from health care providers, researchers, academia, industry, and regulators on various aspects of the design and conduct of clinical trials for antibacterial drug development. The input from this

public workshop will help in developing topics for further discussion.

The agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: June 11, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Proposed Information Quality Guidelines Policy

ACTION: Notice and request for public comment on Proposed Information Quality Guidelines.

SUMMARY: These guidelines should be used to ensure and maximize the quality of disseminated information. The Department's guidelines are based on the guidelines of the Office of Management and Budget (OMB), "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of the Information Disseminated by Federal Agencies" 67 FR 8452 (Feb. 22, 2002). The guidelines are not intended to be, and should not be construed as, legally binding regulations or mandates. These guidelines are intended only to improve the internal management of DHS and, therefore, are not legally enforceable and do not create any legal rights or impose any legally binding requirements or obligations on the agency or the public. Nothing in these guidelines affects any available judicial review of agency action. These guidelines will serve as the minimum standards for quality within the Department. DHS Components may expand upon these guidelines as necessary, and should use these

guidelines to develop or improve their processes for ensuring information disseminated by the Components meet the quality standards. DHS Components should implement processes and mechanisms for receiving, reviewing, and responding to information request that are consistent with these guidelines. DHS Components with existing directives, instructions, and correction processes for information quality may continue to use them, provided they are consistent with the standards and processes established in these guidelines.

The guidelines apply to information disseminated to the public in any medium including textual, graphic, narrative, numerical, or audiovisual forms, including information posted on the Internet. The guidelines also apply to DHS Component-sponsored distribution of information—where the DHS Component directs a third party to distribute information or DHS has the authority to review and approve the information before release. If the Department is to rely on information submitted by a third party that information would need to meet appropriate standards of objectivity and utility.

DATES: Comments are encouraged and will be accepted until July 30, 2010.

Comments: Public comments are invited on the information contained in the proposed policy. Comments on the proposed policy should be submitted electronically to DHS.INFOQUALITY@DHS.GOV.

Obtaining a Copy of the Policy: To obtain a copy of the policy please submit a request to DHS.INFOQUALITY@DHS.GOV (including your address and telephone number).

FOR FURTHER INFORMATION CONTACT: Department of Homeland Security, Information Quality Program Management Office at 202-447-5959.

Richard A. Spires,

Chief Information Officer.

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