

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. FDA-2010-N-0001]

Antibacterial Resistance and Diagnostic Device and Drug Development Research for Bacterial Diseases; Public Workshop
AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop jointly sponsored by the National Institute of Allergy and Infectious Diseases and the Infectious Diseases Society of America (IDSA) regarding scientific and potential research issues in antibacterial drug resistance, rapid diagnostic device development for bacterial diseases, and antibacterial drug development. The workshop will address antibacterial drug resistance, mechanisms of resistance, epidemiology of resistance, and issues in the development of rapid diagnostic devices and antibacterial drugs for the diagnosis and treatment of bacterial diseases. The input from this public workshop will help in developing topics for further discussion.

Dates and Times: The public workshop will be held on July 26, 2010, from 8 a.m. to 5:30 p.m. and on July 27, 2010, from 8 a.m. to 5 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 number) to arworkshop@fda.hhs.gov. Persons without access to the Internet can call Chris Moser or Lori Benner at 301-796-1300 to register. Persons needing a sign language interpreter or other special accommodations should notify Christine Moser or Lori Benner (see **Contact Persons**) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop, jointly sponsored by the National Institute of Allergy and Infectious Diseases and the Infectious Diseases Society of America, regarding scientific issues in antibacterial drug resistance and product development for bacterial diseases. Topics for discussion include the following: (1) An overview and discussion of the scale of the current bacterial resistance problem, (2) current understanding of the science and mechanisms of bacterial resistance, (3) the use of rapid diagnostics in the diagnosis and management of bacterial infections, and (4) the science of antibacterial drug development. The input from this workshop will help in the further consideration of potential areas of research in antibacterial resistance and help in developing topics in antibacterial drug development and rapid diagnostic development 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.

Webcasting: The workshop will be simultaneously webcast. The public may view the live webcast free by registering through IDSA's Web site at <http://www.idsociety.org> until 24 hours prior to the workshop. IDSA will do its best to accommodate members of the public who register after this time. Videotaped workshop presentations will also be available free on IDSA's Web site following the 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 20852. 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. Transcripts will also be available on the Internet at <http://www.fda.gov/FDAgov/Drugs/NewsEvents/ucm211146.htm> approximately 45 days after the workshop.

Dated: June 7, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Request for Information (RFI) on the National Institutes of Health Plan To Develop the Genetic Testing Registry
ACTION: Notice.

SUMMARY: The National Institutes of Health, an agency within the Department of Health and Human Services (HHS), is seeking input and feedback on its plan to develop the Genetic Testing Registry (GTR); a centralized public resource that will provide information about the availability, scientific basis, and usefulness of genetic tests. Submission of test information to the GTR will be voluntary, and the NIH expects to receive wide interest and participation from researchers, test developers, and manufacturers.

SUPPLEMENTARY INFORMATION:
I. Background

The last decade has seen tremendous advances in our knowledge of the genomic and genetic factors involved in health and disease. This increased knowledge has been accompanied by a rapid rise in the availability of genetic tests. Although more than 2,000 genetic tests are available, there is no single public resource that provides information about the validity and usefulness of these tests. The NIH believes that transparent access to such information is vital to facilitate research and to enable informed decision making by patients, caregivers, health care providers, clinical laboratory professionals, payers, and policymakers. Therefore, the NIH is initiating the development of the GTR, an online resource that will provide a centralized location for researchers, test developers, and manufacturers to submit information voluntarily about genetic tests, such as their intended use, validity, and utility. The Registry will serve as a resource for health care providers and patients interested in learning about the tests and easily locating laboratories offering particular genetic tests. By using standard identifiers for genetic tests, GTR can facilitate Health Information Technology (HIT) exchange. The GTR will be a repository of information about genetic tests, not a repository of test results.

On March 18, 2010, the NIH announced that it would be creating the GTR (see <http://www.nih.gov/news/health/mar2010/od-18.htm>). This RFI