

**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](mailto: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.*

[FR Doc. 2010-14048 Filed 6-10-10; 8:45 am]

**BILLING CODE 4160-01-S**

**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

notice is part of the public consultation process referenced in that announcement and described on the NIH GTR Web site: <http://www.ncbi.nlm.nih.gov/gtr/>.

## II. Data Elements

The NIH anticipates that the GTR will contain information on a wide range of genetic tests for inherited and somatic genetic variations, including tests ordered through health care providers and those available directly to consumers. The NIH is interested in comments on the types of tests to include within the GTR, as well as on appropriate data elements to collect about each test. The NIH's working definition of a genetic test, for purposes of the Registry, is a test that involves an analysis of human chromosomes, deoxyribonucleic acid, ribonucleic acid, genes and/or gene products (e.g., enzymes, other types of proteins, and selected metabolites), which is predominantly used to detect heritable or somatic mutations, genotypes, or chromosomal variations in structure or number related to disease, health, and/or personalized medicine.

The NIH expects that the GTR will be most useful to health care providers, patients and consumers, clinical laboratory professionals, policymakers, and researchers if it includes information on the validity and utility of genetic tests. This expectation is consistent with recommendations of the HHS Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS).<sup>i</sup> Validity includes both analytical validity (a test's ability to measure the analyte or genotype of interest accurately and reliably) and clinical validity (the relationship between a test result and health outcome or phenotype). Utility is the net balance of risks and benefits associated with using a test<sup>i</sup> and includes both clinical utility and personal utility.

To assist researchers, consumers, and providers in fully understanding a test, it will be important to include information about its molecular basis, including, for example, information about what the test detects and what methods the test employs. Supporting evidence for a test's clinical validity and/or utility may include published data, systematic reviews, and practice guidelines.

The NIH is particularly interested in receiving comments on the type of data elements that should be included in the GTR and the level of information that would adequately address these data elements.

## III. Request for Comments

The NIH is seeking input and advice on the following items:

1. Are there any types of genetic tests that should not be included in the GTR?

2. What are the potential uses of the GTR for (1) researchers, (2) patients/consumers, (3) health care providers, (4) clinical laboratory professionals, (5) payers, (6) genetic testing entities/data submitters, (7) policymakers, and (8) electronic health records?

3. What data elements are critical to include for use by (1) researchers, (2) patients/consumers, (3) health care providers, (4) clinical laboratory professionals, (5) payers, (6) genetic testing entities/data submitters, (7) policymakers, and (8) electronic health records?

4. What are the potential benefits and risks associated with facilitating public access to information about the:

a. Availability and accessibility of genetic tests?

b. Scientific basis and validity of genetic tests?

c. Utility of genetic tests?

5. What is the best way to distinguish between data fields left blank because of an absence of data/evidence and those left blank for other reasons? How important is this distinction for enhancing transparency, including for the purpose of identifying research opportunities?

6. To describe adequately and accurately a genetic test, which of the following data elements should be included in the GTR? Are there other data elements that should be added? What information is necessary to represent adequately each data element?

a. Contact information (e.g., location, name of the laboratory director, and contact information for the laboratory performing the test)

b. Laboratory certifications (e.g., Federal or State certification of the laboratory that performs the test)

c. Name of the test (e.g., common test name, commercial name, marketing materials about the test and/or genetic testing entity, standard identifier (e.g., CPT codes, LOINC<sup>ii</sup>))

d. Regulatory clearances (e.g., for tests reviewed by the Food and Drug Administration, the 510(k) or premarket approval (PMA) number)

e. Intended use of the test (e.g., diagnosis, screening, drug response)

f. Recommended patient population

g. Limitations of the test (e.g., is the test validated only for certain subpopulations or limited to particular uses such as screening but not diagnostic testing?)

h. Test methodology

i. Analyte(s)—What is being measured in the test (e.g., genetic sequence)

j. Specimen requirements (e.g., blood, saliva, tissue samples, amniotic fluid)

k. Availability (e.g., is the submitter the sole provider of the test or are there multiple providers?)

l. Accessibility (e.g., accessible through a health provider, public health mandate, and/or direct-to-consumer)

m. Performance characteristics<sup>i</sup>

i. Analytical sensitivity

ii. Analytical specificity

iii. Accuracy

iv. Precision

v. Reportable range of test results

vi. Reference range

vii. Method used for proficiency testing (e.g., formal PT program, alternative assessment) and score

n. Clinical validity<sup>i</sup>

i. Clinical sensitivity

ii. Clinical specificity

iii. Positive and negative predictive value

iv. Prevalence

v. Penetrance

vi. Modifiers

o. Utility (e.g., clinical and/or personal utility) or outcomes

i. Benefits

ii. Harms

iii. Added value, compared with current management without genetic testing

p. Cost (e.g., price of the test, health insurance coverage)

7. What types of information might be difficult for test providers to submit and why?

8. What are the advantages and disadvantages of collecting and providing information on the molecular basis of genetic tests, such as detailed information about what the test detects and the specific methods employed?

9. In addition to the data elements, would it be helpful to reference other resources, and if so, which ones (e.g., published studies, recommendations from expert panels such as the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, U.S. Preventive Services Task Force, or Evaluation of Genomic Applications in Practice and Prevention Working Group)?

10. As the GTR is being designed, what are the important processes to consider to make the submission of data as easy as possible for the data provider (e.g., the capability of linking to information that has been submitted to other agencies, such as the Food and Drug Administration and the Centers for Medicare and Medicaid Services, or a master file of data common to particular tests)?

11. Which potential benefits and risks would be most likely to affect the

decisions of researchers, test developers, and manufacturers on whether to submit data to the GTR, and what factors will best encourage submission of complete and accurate data?

12. What are the most effective methods to ensure continued stakeholder input into the maintenance of the GTR?

13. For what purpose(s) would you use the Registry to support your professional efforts?

14. Are there any other issues that NIH should consider in the development of the GTR?

**DATES:** To assure consideration, comments must be received by July 12, 2010.

**ADDRESSES:** Individuals, groups, and organizations interested in commenting on the NIH plan to develop the GTR, as outlined in this RFI, may submit comments by e-mail to [GTR@od.nih.gov](mailto:GTR@od.nih.gov) or by mail to the following address: NIH GTR RFI Comments, National Institutes of Health, Office of Science Policy, 6705 Rockledge Drive, Room 750, Bethesda, MD 20892. Comments will be made publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

**FOR FURTHER INFORMATION CONTACT:** Dr. Cathy Fomous, NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Room 750, Bethesda, MD 20892; telephone 301-496-9838; fax 301-496-9839; e-mail [CFomous@od.nih.gov](mailto:CFomous@od.nih.gov).

Dated: June 4, 2010.

**Francis S. Collins,**

*Director, National Institutes of Health.*

## Footnotes

<sup>i</sup> From the HHS Secretary's Advisory Committee on Genetics, Health and Society 2008 Report, *U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services*, available at [http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS\\_oversight\\_report.pdf](http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_oversight_report.pdf).

<sup>ii</sup> Logical Observation Identifiers Names Codes (LOINC), a standard for unambiguous identification of tests and other measurements in health information exchange. Available at <http://loinc.org>. LOINC is a required standard in the certification criteria for electronic health records issued by the National Coordinator for Health Information Technology, HHS (<http://edocket.access.gpo.gov/2010/E9-31216.htm>), to facilitate health information exchange.

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### United States Immigration and Customs Enforcement

#### Agency Information Collection Activities: New Information Collection; Comment Request

**ACTION:** 60-Day Notice of New Information Collection; ICE Mutual Agreement Between Government and Employers (IMAGE).

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (ICE), is submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until August 10, 2010.

Written comments and suggestions regarding items contained in this notice, and especially with regard to the estimated public burden and associated response time should be directed to the Department of Homeland Security (DHS), Joseph M. Gerhart, Chief, Records Management Branch, U.S. Immigration and Customs Enforcement, 500 12th Street, SW., Room 3138, Washington, DC 20536; (202) 732-6337.

Comments are encouraged and will be accepted for sixty days until August 10, 2010. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

## Overview of This Information Collection

(1) *Type of Information Collection:* New information collection.

(2) *Title of the Form/Collection:* ICE Mutual Agreement between Government and Employers (IMAGE) Information Request and Membership Application.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form 73-028, U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Businesses or other for-profit and not-for-profit institutions. The Immigration and Customs Enforcement Mutual Agreement between Government and Employers (IMAGE) program is the outreach and education component of the Office of Investigations (OI) Worksite Enforcement (WSE) program. IMAGE is designed to build cooperative relationships with the private sector to enhance compliance with immigration laws and reduce the number of unauthorized aliens within the American workforce. Under this program ICE will partner with businesses representing a cross-section of industries. A business will initially complete and prepare an IMAGE membership application so that ICE can properly evaluate the company for inclusion in the IMAGE program. The information provided by the company plays a vital role in determining its suitability for the program.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 100 responses at 90 minutes (1.5 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 150 annual burden hours.

Requests for a copy of the proposed information collection instrument, with instructions; or inquiries for additional information should be requested via e-mail to: [forms.ice@dhs.gov](mailto:forms.ice@dhs.gov) with "IMAGE Program Application" in the subject line.

Dated: June 3, 2010.

**Joseph M. Gerhart,**

*Chief, Records Management Branch, U.S. Immigration and Customs Enforcement, Department of Homeland Security.*

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**BILLING CODE P**