

accommodations should notify Chris Moser or Lori Benner (see *Contact Person*) at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** FDA is announcing a public workshop, cosponsored with IDSA, regarding antimicrobial drug development. This public workshop will focus on scientific considerations in designing clinical trials for community-acquired pneumonia. The topics for discussion include approaches to the diagnosis of community-acquired pneumonia, the effect of antimicrobial treatment for community-acquired pneumonia, various endpoints that might be considered as endpoints for trials of community-acquired pneumonia, and statistical issues in analysis of results from trials in community-acquired pneumonia. 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:* Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, approximately 20 working days after the public workshop, at a cost of 10 cents per page.

Dated: December 18, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007N-0480]

#### Maximizing the Public Health Benefit of Adverse Event Collection Throughout a Product's Marketed Life Cycle; Public Workshop; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) are announcing a public workshop entitled "Maximizing the Public Health Benefit of Adverse

Event Collection Throughout a Product's Marketed Life Cycle." The purpose of the public workshop is to solicit information and views from interested persons on research approaches and methods associated with the best ways to assess the public health benefit of collecting and reporting all adverse events (AEs). The input from this workshop will be used to publish a request for information to determine the types of outside organizations that would be interested in, and have the capability to conduct, the research described in this paragraph, followed by a request for proposal (RFP).

**DATES:** The public workshop will be held on January 29, 2008, from 8:30 a.m. to 5 p.m. Individuals who wish to speak during the public workshop must register on or before January 15, 2008. See section III of this document for information on how to attend or present at the meeting.

We are opening a docket to receive your written or electronic comments. Written or electronic comments must be submitted to the docket by February 29, 2008.

**ADDRESSES:** The public workshop will be held at The Conference Facility (terrace level) located at 5635 Fishers Lane, Rockville, MD 20857 (Metro: Twinbrook Station on the Red Line).

Submit written or electronic comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

**FOR FURTHER INFORMATION CONTACT:** Lana Pauls, Center for Drug Evaluation and Research (HFD-006), Food and

Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-0518, FAX: 301-827-1069, e-mail: [lana.pauls@fda.hhs.gov](mailto:lana.pauls@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The collection of information relating to AEs is an integral part of understanding the safety of a product throughout its marketed life cycle. FDA is committed to maximizing the public health benefit of collecting and reporting serious and non-serious AEs. Central to addressing this question is determining the number and type of safety concerns discovered by AE collection, the age of products at the time safety concerns are detected by AE collection, and the types of actions that are subsequently taken to protect patient safety.

The workshop objectives are as follows: (1) Initiate constructive dialogue and information-sharing among regulators, researchers, the pharmaceutical industry, health organizations, and individuals affected by postmarketing AE collection, reporting, and evaluation; (2) share current FDA practices regarding postmarketing AE collection and reporting; and (3) obtain input on the questions and methods that will be used to conduct research on this topic.

Two panel discussions will focus on how FDA currently uses spontaneous reports and other methods of signal detection, the key research questions that should be addressed by the RFP, and appropriate research approaches and methods including, but not limited to, hypothesis, study design, data sources, outcome measures, and analytic methods. Panel one will focus on the key research questions; panel two will discuss research approaches and methods.

Some of the key questions to be addressed in the RFP include the following:

(1) What is the value to patient safety of collecting AEs through a passive surveillance system over the marketed life cycle of a product? How are these data best used in regulatory decision-making?

(2) How can safety issue identification and subsequent regulatory action be characterized in relation to time elapsed following product approval? Is this influenced by the type of regulatory action and/or the nature of the safety signal?

(3) What are the roles of serious and non-serious outcome reports in safety issue identification and subsequent regulatory action? How do the roles of

these report types change over the product's marketed life cycle?

(4) What are the roles of reports by health care professionals and consumers in safety signal detection?

(5) Are there any types of AE reports that are not helpful to safety signal detection?

(6) What do we know about non-reported AEs or characteristics associated with non-reporting?

FDA is working to refine the workshop agenda and to invite panel members. We are seeking broad participation by safety researchers, health system officials, the pharmaceutical industry, and others. We anticipate issuing a summary of the workshop findings, including a discussion of implications and next steps for further development.

**II. Comments**

The agency is interested in hearing comments at the public workshop or receiving written comments (see ADDRESSES) on the issues described previously. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. Attendance and Registration**

The Conference Facility (terrace level) located at 5635 Fishers Lane is a Federal facility with limited seating and security procedures for entrance. Workshop attendees will be required to show proper identification and are asked to allow time for security procedures. Seating will be made available on a first-come basis. Individuals who wish to speak during the public workshop must register on or before January 15, 2008. You should identify the subject matter you wish to address during the public workshop. Please specify either panel one or panel two (see section I of this document). To register to speak, please contact Lana Pauls (see FOR FURTHER INFORMATION CONTACT).

Ample time will be allowed during the scheduled agenda for attendees to ask questions of panelists. In addition, we strongly encourage written comments to the docket.

If you need special accommodations because of disability, please contact

Lana Pauls (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the workshop.

**IV. Workshop Transcripts**

The workshop will be transcribed. The transcript will be available for review at the Division of Dockets Management (see ADDRESSES) and on the Internet at <http://www.fda.gov/ohrms/dockets>, approximately 30 days after the workshop.

Dated: December 18, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Division of Loan Repayment; Proposed Collection; Comment Request; National Institutes of Health Loan Repayment Programs**

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Division of Loan Repayment, National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection: Title:* National Institutes of Health Loan Repayment Programs. *Type of Information Collection Request:* Revision of currently approved collection (OMB No. 0925-0361, expiration date 6/30/08). *Form Numbers:* NIH 2674-1, NIH 2674-2, NIH 2674-3, NIH 2674-4, NIH 2674-5, NIH 2674-6, NIH 2674-7, NIH 2674-8, NIH 2674-9, NIH 2674-10, NIH 2674-11, NIH 2674-12, NIH 2674-13, NIH 2674-14, NIH 2674-15, NIH 2674-16, NIH 2674-17, NIH 2674-18, and NIH 2674-19. *Need and Use of Information Collection:* The NIH makes available financial assistance, in the form of educational loan repayment, to M.D., Ph.D., Pharm.D., D.D.S., D.M.D.,

D.P.M., D.C., and N.D. degree holders, or the equivalent, who perform biomedical or behavioral research in NIH intramural laboratories or as extramural grantees for a minimum of 2 years (3 years for the General Research Loan Repayment Program (LRP)) in research areas supporting the mission and priorities of the NIH.

The AIDS Research Loan Repayment Program (AIDS-LRP) is authorized by Section 487A of the Public Health Service Act (42 U.S.C. 288-1); the Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR-LRP) is authorized by Section 487E (42 U.S.C. 288-5); the General Research Loan Repayment Program (GR-LRP) is authorized by Section 487C (42 U.S.C. 288-3); the Loan Repayment Program Regarding Clinical Researchers (LRP-CR) is authorized by Section 487F (42 U.S.C. 288-5a); the Pediatric Research Loan Repayment Program (PR-LRP) is authorized by Section 487F (42 U.S.C. 288-6); the Extramural Clinical Research LRP for Individuals from Disadvantaged Backgrounds (ECR-LRP) is authorized by an amendment to Section 487E (42 U.S.C. 288-5); the Contraception and Infertility Research LRP (CIR-LRP) is authorized by Section 487B (42 U.S.C. 288-2); and the Health Disparities Research Loan Repayment Program (HD-LRP) is authorized by Section 485G (42 U.S.C. 287c-33).

The Loan Repayment Programs provide for the repayment of up to \$35,000 a year of the principal and interest of the educational loan debt of qualified health professionals who agree to conduct qualifying research for each year of obligated service. The information proposed for collection will be used to determine an applicant's eligibility for participation in the program. *Frequency of Response:* Initial application and annual or biennial renewal application. *Affected Public:* Applicants, financial institutions, research institutions, recommenders. *Type of Respondents:* Physicians, other scientific or medical personnel, and organizational officials. The annual reporting burden is as follows:

Type of respondents	Number of respondents	Estimated number of responses per respondent	Average burden hours per response	Annual burden hours requested
<i>Intramural LRPs</i>				
Initial Applicants .....	30	1	10.11	303.30
Advisors/Supervisors .....	30	1	.5	15.00
Recommenders .....	90	1	.33	29.70
Financial Institutions .....	10	1	1.25	12.50