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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.

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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*.

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 FORTHER 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.

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Dated: December 18, 2007.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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