

hours for the purpose of this information collection.

The majority of the burden for developing the patient labeling is included under the reporting requirements; therefore, minimal burden is calculated for providing the guide to patients. As discussed previously, no burden can be calculated at this time for the number of AER reports that may be submitted after approval of a new drug or biologic. Therefore, the number of records that may be maintained also cannot be determined. Any burdens associated with these requirements will be reported under the AER information collection requirements. The estimated recordkeeping burden of 1 hour is based on previous estimates for the recordkeeping requirements associated with the AER system.

FDA, in the **Federal Register** of November 13, 2002 (67 FR 68874), the agency requested comments on the proposed collection of information. No comments were received.

Dated: February 28, 2003.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. 02N-0528]

#### **Risk Management; Public Workshop**

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

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

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop to discuss risk management activities for drug and biological products (excluding blood products other than plasma derivatives). The purpose of the workshop is to present FDA's current thoughts on risk management activities and to solicit views from the public. To facilitate public input and discussion, FDA is issuing for review and comment three concept papers that focus on risk assessment, risk management, and pharmacovigilance. The input received at the workshop and from comments on the concept papers will be considered in drafting guidance for industry.

**DATES:** The public workshop will be held on April 9, 10, and 11, 2003, from

8 a.m. to 4:30 p.m. Submit written or electronic requests to preregister to speak by March 21, 2003. Written or electronic comments on the concept papers will be accepted until April 30, 2003. However, to have your comments considered at the workshop, submit them by March 21, 2003.

**ADDRESSES:** The public workshop will be held at the National Transportation Safety Board Boardroom and Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594; 202-314-6421. The center may be reached by Metro, using the L'Enfant Plaza Station on the green, yellow, blue, and orange lines) <http://www.nts.gov/events/newlocation.htm>. Seating is limited and will be available on a first-come first-served basis each day of the workshop.

Submit written or electronic requests to speak and comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852; e-mail [FDADockets@oc.fda.gov](mailto:FDADockets@oc.fda.gov); or on the Internet at <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Transcripts of the workshop will be available for review at the Dockets Management Branch (see address above) and on the Internet at <http://www.fda.gov/ohrms/dockets>.

#### **FOR FURTHER INFORMATION CONTACT:**

*For media and press inquiries:* Jason Brodsky, Office of Public Affairs (HFI-020), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301-827-6242, [jbrodsky@oc.fda.gov](mailto:jbrodsky@oc.fda.gov).

*For all other inquiries:* Lee Lemley, Center for Drug Evaluation and Research (HFD-006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-6218, [lemleyl@cder.fda.gov](mailto:lemleyl@cder.fda.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

On June 12, 2002, the President signed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188), which includes the Prescription Drug User Fee Amendments of 2002 (Public Law 102-571) (PDUFA 3). In exchange for receiving user fees under PDUFA 3, FDA agreed to certain performance goals. As one of its PDUFA 3 goals, FDA agreed to produce guidance for industry on risk management activities. Specifically, FDA intends to produce three guidance documents by September 30, 2004, addressing: Good risk assessment, risk management, and pharmacovigilance practices for drug and biological

products (excluding blood products other than plasma derivatives). As an initial step, three joint Center for Drug Evaluation and Research (CDER)/Center for Biologics Evaluation and Research (CBER) working groups have developed concept papers outlining FDA's preliminary thoughts for providing guidance for industry. The concept papers are available at FDA's Dockets Management Branch and on the Internet (<http://www.fda.gov/cder/meeting/riskmanagement.htm>). FDA welcomes written and electronic comments on the concept papers (see section IV of this document).

##### **II. Scope of Workshop and Concept Papers**

At this public workshop, FDA is interested in receiving comments from stakeholder groups likely to be affected by its risk management activities. Stakeholder groups of interest include, but are not limited to: Consumer groups, physicians, nurses, pharmacists, drug and biological product manufacturers, and third party payers for health care services and medical products.

Each day of the 3-day workshop will focus on one aspect of risk management activities, including: (1) Premarketing risk assessment on April 9, 2003, (2) risk management programs and planning on April 10, 2003, and (3) pharmacovigilance and pharmacoepidemiologic assessment on April 11, 2003.

##### *A. Premarketing Risk Assessment (April 9, 2003)*

Risk assessment is the process of identifying, estimating, and evaluating the nature and severity of risks associated with a product throughout its lifecycle. On April 9, 2003, the public workshop discussion will focus on good risk assessment practices during product development. Specifically, the discussion will focus on issues raised by the concept paper "Premarketing Risk Assessment" (<http://www.fda.gov/cder/meeting/riskmanagement.htm>). This concept paper presents FDA's preliminary thoughts on:

1. Important risk assessment concepts,
2. Generation and acquisition of safety data during clinical trials, and
3. Analysis and presentation of safety data in an application for approval

##### *B. Risk Management Programs and Planning (April 10, 2003)*

Risk management is the overall and continuing process of minimizing risks throughout a product's lifecycle to optimize its benefit/risk balance. On April 10, 2003, the public workshop discussion will focus on the