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.

[FR Doc. 03–5357 Filed 3–6–03; 8:45 am]

BILLING CODE 4160–01–S

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.ntsb.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; 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.

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.

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

development, implementation, and evaluation of strategic safety programs designed to decrease a product's risks. Specifically, the discussion will focus on issues raised by the concept paper ''Risk Management Programs'' (http://www.fda.gov/cder/meeting/riskmanagement.htm). This concept paper presents FDA's preliminary thoughts on:

1. Considerations on what comprises and prompts a risk management program,
2. The selection and development of risk management tools,
3. The evaluation of risk management programs, and
4. The recommended elements of a risk management program submission to FDA.

Comments on evaluation methods and overall concepts are requested, in particular, from academicians and others with experience in outcomes research in health care quality or pharmacoepidemiology.

C. Risk Assessment of Observational Data: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment (April 11, 2003)

Pharmacovigilance is generally regarded as all postapproval scientific and data gathering activities relating to the detection, assessment, understanding, and prevention of adverse events or any other product-related problems. On April 11, 2003, the public workshop discussion will focus on the assessment of a product's risk profile as identified from observational data sources (including case reports, case series, and pharmacoepidemiologic studies). Specifically, the discussion will focus on issues raised by the concept paper ''Risk Assessment of Observational Data: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment'' (http://www.fda.gov/cder/meeting/riskmanagement.htm). This concept paper presents FDA's preliminary thoughts on:

1. Important pharmacovigilance concepts,
2. Safety signal identification,
3. Pharmacoepidemiologic assessment and interpretation of safety signals, and
4. The development of pharmacovigilance plans.

In particular, in this segment of the public workshop, FDA is interested in receiving public input on the following questions:

1. How can the quality of spontaneously reported case reports be improved?
2. What are possible advantages or disadvantages of applying datamining techniques (e.g., empirical Bayesian techniques, proportional reporting ratios) to spontaneous reports databases for the purpose of identifying safety signals?
3. What are possible advantages or disadvantages of performing causality assessments at the individual case level?
4. Under what circumstances would a registry be useful as a surveillance tool and when would it cease to be useful?
5. Under what circumstances would active surveillance strategies prove useful to identify as yet unreported adverse events?
6. Under what circumstances would additional pharmacoepidemiologic studies be useful?

III. Registration and Requests for Oral Presentations

To speak at the workshop you must preregister by March 21, 2003. Requests must be submitted electronically or in writing. In your request to speak, you should state the: (1) Day of the workshop when you would like to speak; (2) specific issue related to that day's topic that you intend to address; (3) names and addresses of all individuals that plan to participate; and (4) approximate time requested to make your presentation. Electronic requests to speak at the workshop may be submitted at http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm. Requests to speak will be accepted on a first-come, first-served basis. Individuals who register to speak will be notified of the scheduled time for their presentation before the workshop and will have reserved seating. Depending on the number of speakers, FDA may need to limit the time allotted for each presentation. Speakers must submit two copies of each presentation by the date they have registered to speak. If you need special accommodations due to a disability, please inform the registration contact person when you register. Presentations should be limited to the topics addressed in the concept papers. Preregistration is not necessary if you are not speaking and plan to come only as an attendee to the workshop. However, seating is limited and will be available on each of the workshop days on a first-come first-served basis.

IV. Request for Comments

Regardless of attendance at the workshop, interested persons may submit written or electronic comments on the concept papers to the Dockets Management Branch (see **ADDRESSES**). You should annotate and organize your comments to identify the specific concept paper and issue to which they refer. Where possible, comments should reference line numbers in the concept papers. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The concept papers and received comments may be seen at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Transcripts of the hearing also will be available for review at the Dockets Management Branch.

V. Electronic Access

Electronic versions of the concept papers are available via Internet using the World Wide Web at http://www.fda.gov/cder/meeting/riskmanagement.htm.

Dated: March 3, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the 36th meeting of the Substance Abuse and Mental Health Service Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) National Advisory Council will be held in March 2003.

A portion of the meeting is open and includes discussion of the Center's policy issues and current administrative, legislative, and program developments. The Council's meeting will include reports on SAMHSA's Faith-Based and Community Initiative; Pregnant and Postpartum Women (PPW) & Residential Women and Children (RWC) Cross Site Evaluations; Oral Fluid Testing; Science to Services; Methadone Deaths; and SAMHSA's Co-Occurring Report to Congress. In addition, the CSAT Director will provide an update on CSAT's program and activities.

The meeting will also include the review, discussion, and evaluation of individual grant applications. Therefore a portion of the meeting will be closed to the public as determined by the SAMHSA Administrator, in accordance