

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