DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 2005N–0394]

Food and Drug Administration's Communication of Drug Safety Information; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA) is announcing a public hearing on the Center's current risk communication strategies for human drugs. The public hearing announced in this notice is part of the agency's ongoing effort to improve CDER's risk communication. The purpose of the public hearing is to obtain public input on CDER's current risk communication tools, identify stakeholders for collaboration and implementation of additional tools, and obtain greater understanding of the strengths and weaknesses of CDER's existing risk communication.

DATES: The public hearing will be held on December 7 and 8, 2005, from 8 a.m. to 4:30 p.m. Submit written or electronic notices of participation and comments for consideration at the hearing by November 7, 2005. Written or electronic comments will be accepted after the hearing until January 9, 2006. The administrative record of the hearing will remain open until January 9, 2006.

ADDRESSES: The public hearing will be held at the National Transportation and Safety Board Boardroom and Conference Center, 429 L'Enfant Plaza, SW.,

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Washington, DC 20594 (Metro: L'Enfant Plaza Station on the Green, Yellow, Blue, and Orange Lines). Submit written or electronic notices of participation and comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852; *http://www.fda.gov/dockets/ecomments.* Transcripts of the hearing will be available for review at the Division of Dockets Management and on the Internet at *http://www.fda.gov/ohrms/dockets/default.htm* approximately 30 days after the hearing.

FOR FURTHER INFORMATION CONTACT: Lee Lemley, Office of Executive Programs (HFD–006), Center for Drug Evaluation and Research, Food and Drug Administration, 5515 Security Lane, rm. 5107, Rockville, MD 20852, 301–443–5575.

SUPPLEMENTARY INFORMATION:

I. Background

FDA approves human drugs and therapeutic biologics when the agency determines that the benefits of using a product outweigh the risks for the intended population and use. Once a drug product is marketed, however, ensuring its safety becomes a complicated responsibility shared by many parties. These include health care professionals (who must weigh both the risks and the benefits of drugs in deciding whether to prescribe a particular drug for a particular patient to achieve an optimal therapeutic outcome); patients and caregivers (who must understand both the benefits and risks of drugs so they can have informed discussions with their health care professionals about their medicines and make informed decisions about their use); manufacturers, and others. Therefore, it is critical that risk communication be timely, accurate, and easily accessible. Information must also be communicated in a way that

recognizes health literacy limitations, including the needs of a multicultural population.

In May 1999, FDA published "Managing the Risks From Medical Product Use," which laid a framework for the agency's efforts to reduce the risks involved with medical product use. In February 2005, the Department of Health and Human Services Secretary Mike Leavitt and former FDA Commissioner Lester Crawford announced plans to establish new communication channels and expand existing channels to provide targeted drug safety information to the public.

Although outside the scope of this hearing, FDA-approved human drug labeling is the primary tool the agency uses to communicate risk and benefit to the public. However, CDER also provides drug safety information to the public through a variety of other risk communication tools. For example, FDA has recently initiated communication tools called Patient and Healthcare Professional Information Sheets. In addition, FDA releases Talk Papers, Public Health Advisories, Press Releases, MedWatch Safety Updates and a monthly video news program for health professionals called the Patient Safety News. FDA also conducts educational campaigns and conveys drug safety information through the CDER Internet site (*http://www.fda.gov/cder*).

II. Scope of the Hearing

FDA is interested in obtaining public comment on the following risk communication tools:

- Patient Information Sheets (for example, see: *http://www.fda.gov/cder/drug/infosheets/patient/adderallpt.htm*)
- Healthcare Professional Information Sheets (for example, see: *http://www.fda.gov/cder/drug/infosheets/hcp/fluoxetinehcp.htm*)
- Talk Papers (for example see: *http://www.fda.gov/opacom/hpnews.html*)

- Public Health Advisories (for example, see: *http://www.fda.gov/cder/news/pubpress.htm*)
- Press Releases (for example, see: *http://www.fda.gov/opacom/hpnews.html*)
- MedWatch Listserv Safety Updates (*http://www.fda.gov/medwatch/index.html*)
- Patient Safety News (*http://www.fda.gov/psn*)
- CDER Educational Campaigns (for example see: *http://www.fda.gov/cder/drug/analgesics/default.htm*)
- CDER Internet site (*http://www.fda.gov/cder*)

Specifically, FDA is inviting public comment from external stakeholders on the following issues:

1. What are the strengths and weaknesses of the communication tools listed previously in this section of the document?

2. What information is available about awareness, use, and perceptions of the effectiveness of these communication tools by health care professionals and by the public in general?

3. Do these tools provide the right kind and amount of risk and other information that health care professionals need to make informed decisions about whether to prescribe drug products, and that the public needs to make informed decisions about whether to use those products?

4. How easily accessible and understandable are FDA's Internet-based sources of drug information?

5. To what extent do CDER's patient-focused communication tools provide useful information for people with low health literacy skills?

6. What mechanisms should CDER consider to convey risk information to special populations (e.g., elderly, non-English speaking)?

The following topics are outside the scope of this hearing: Consumer medication information (and the draft guidance entitled "Useful Written Consumer Medication Information [CMI]"); industry promotional materials, including Direct to Consumer Advertising; drug labeling (including Medication Guides and patient package inserts); and the draft guidance entitled "FDA's 'Drug Watch' for Emerging Drug Safety Information." Comments have been solicited on these issues at other times in separate proceedings.

III. Notice of Hearing Under 21 CFR Part 15

The Acting Commissioner of Food and Drugs (the Acting Commissioner) is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The presiding officer will be the Acting Commissioner or his designee. The presiding officer will be accompanied by a panel of FDA employees with relevant expertise.

Persons who wish to participate in the part 15 hearing must file a written or electronic notice of participation with the Division of Dockets Management (see **ADDRESSES** and **DATES**). To ensure timely handling, any outer envelope should be clearly marked with the docket number listed in brackets in the heading of this notice along with the statement "FDA's Communication of Drug Safety Information; Public Hearing." Groups should submit two written copies. The notice of participation should contain the potential presenter's name; address; telephone number; affiliation, if any; the sponsor of the presentation (e.g., the organization paying travel expenses or fees), if any; a brief summary of the presentation; and the approximate amount of time requested for the presentation. The agency requests that interested persons and groups having similar interests consolidate their comments and present them through a single representative. After reviewing the notices of participation and accompanying

information, FDA will schedule each appearance and notify each participant of the time allotted to the presenter and the approximate time that presenter's oral testimony is scheduled to begin. If time permits, FDA may allow interested persons attending the hearing who did not submit a written or electronic notice of participation in advance to make an oral presentation at the conclusion of the hearing. The hearing schedule will be available at the hearing. After the hearing, the schedule will be placed on file in the Division of Dockets Management (see **ADDRESSES**) under the docket number listed in brackets in the heading of this notice.

Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C). Under § 10.205 (21 CFR 10.205), representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b). The transcript will be available on the Internet at *http://www.fda.gov/ohrms/dockets/default.htm*, and orders for copies of the transcript can be placed at the meeting or through the Division of Dockets Management (see **ADDRESSES**).

Any handicapped persons requiring special accommodations to attend the hearing should direct those needs to the contact person (see **FOR FURTHER INFORMATION CONTACT**).

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of these provisions as specified in § 15.30(h).

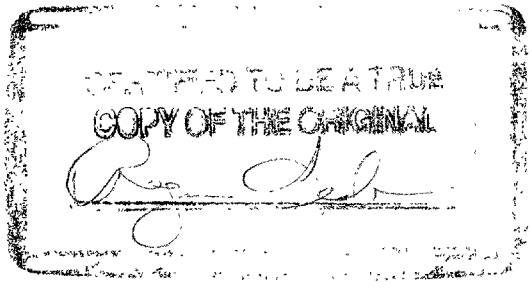
IV. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic notices of participation and comments for consideration at the hearing (see **DATES**). Submit a single copy of written or electronic notices of participation and comments, or two paper copies of any mailed notices of participation and comments, 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 9/26/05
September 26, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

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