

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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[Docket No. 02N-0115]

DMB

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Certifier D. Hawkins

**Risk Management of Prescription Drugs; Public Hearing**

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

**ACTION:** Notice of public hearing; request for comments.

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**SUMMARY:** The Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA) is announcing a public hearing on the agency's approach to risk management of prescription drugs. 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. The public hearing announced in this notice is part of the agency's ongoing efforts to improve CDER's risk communication and to develop new and effective risk management tools. The purpose of the hearing is to obtain public input on improving risk management of prescription drugs; identify stakeholders for further collaboration on development and implementation of risk management tools; obtain greater understanding of the strengths and weaknesses of existing risk management tools, which should help guide improvements or creation of new tools; and obtain input on strategies to assess the effectiveness of tools used for risk management of prescription drugs.

**DATES:** The public hearing will be held on Wednesday, May 22, 2002, from 8 a.m. to 4:30 p.m. Submit written or electronic notices of participation and comments for consideration at the hearing by April 23, 2002. Written or electronic comments will be accepted after the hearing until June 21, 2002.

**ADDRESSES:** The public hearing will be held at the National Transportation Safety Board Boardroom and Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594 (Phone: 202-

314-6421; Metro: L'Enfant Plaza Station on the green, yellow, blue, and orange lines). Submit written or electronic notices of participation and comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852; email: FDADockets@oc.fda.gov; or on the Internet at <http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm>. Transcripts of the hearing will be available for review at the Dockets Management Branch (address above) and on the Internet at <http://www.fda.gov/ohrms/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Christine Bechtel, Center for Drug Evaluation and Research (HFD-006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5458, [bechtelc@cder.fda.gov](mailto:bechtelc@cder.fda.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA approves medical products when the agency determines that the benefits of using a product outweigh the risks for the intended population and use. The product must be labeled with adequate information on its risks and benefits. The labeling must also provide sufficient information to ensure the product is safely used to produce the stated effect. Labeling is given considerable emphasis because it is the primary tool the agency uses to communicate risk and benefit to the public. Once the medical product is marketed, however, ensuring safety becomes a complicated responsibility shared by many parties, including health care providers, manufacturers, patients, and others. New information on safety that needs dissemination often arises postmarketing. Occasionally, a product's safety and efficacy profile changes, resulting in the need for safety intervention beyond labeling (e.g., to protect the public or a population subgroup from increased risks). When such situations arise, effective risk management tools are needed.

Many critics have expressed concern that the current risk management system for drugs is inadequate. The number of drugs available on the market is increasing along with their complexity. The potential for interactions among various treatments is also growing and is beyond the ability

of many busy physicians to track. In addition, changes in the health care delivery system, advertising, third-party payer programs, and other forces are challenging the current risk management system. Recent studies of the effectiveness of FDA's traditional risk communication tools (i.e., the "dear health care practitioner letter" and the black box warning in product labeling) have demonstrated that these tools have limited effect in changing the behavior of health care providers with regard to prescribing and monitoring patients' health (Refs. 1, 2, and 3).

## II. Scope of the Hearing

FDA is interested in obtaining public comment on the following issues:

### A. Risk Communication

- What improvements are needed to enhance communication about safety issues for drugs?
- What improvements are needed to communicate information about the efficacy of drugs?
- What are the strengths and weaknesses of the agency's current risk labeling approach?
- How can communication with health care practitioners become more effective (e.g., improve the "dear health care practitioner letter" and other current communication strategies)?
- What other steps should FDA be taking to communicate risks and benefits?

### B. Tools for Risk Management

- What methods should FDA be using to manage risk?
- What new tools can be created to better address specific drug risks?
- What are the advantages and disadvantages of restricted marketing as a risk management tool?
- What risk interventions can FDA initiate for pharmacists, physicians, patients, and drug manufacturers?

### C. Evaluation of Risk Management Strategies and Interventions

- What risk management interventions should be studied for effectiveness?

- What criteria should be used to judge if a risk management intervention is effective?

### III. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs (the 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 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 Dockets Management Branch (see **ADDRESSES**) before April 23, 2002. To ensure timely handling, any outer envelope should be clearly marked with the docket number listed at the head of this notice along with the statement "Risk Management of Prescription Drugs Hearing." Groups should submit two written copies. The notice of participation should contain the person'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 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 by telephone of the time allotted to the person and the approximate time the person's oral presentation 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 hearing schedule will be placed on file in the Dockets Management Branch under the docket number listed at the head 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 (part 10, subpart C (21 CFR part 10, subpart C)). Under § 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 of the hearing will be available on the Internet at <http://www.fda.gov/ohrms/dockets>, and orders for copies of the transcript can be placed at the meeting or through the Dockets Management Branch (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**).

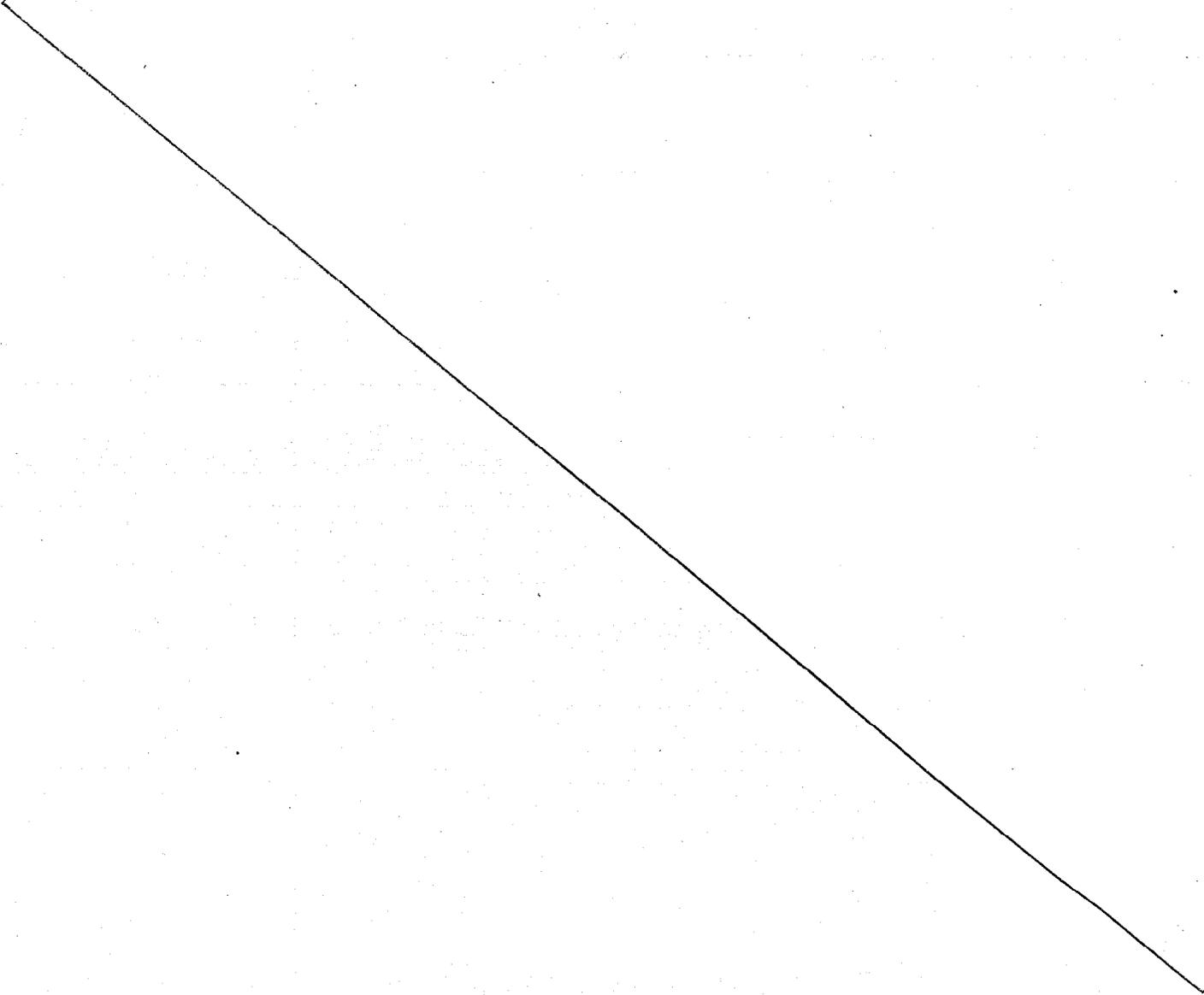
To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

#### **IV. Request for Comments**

Interested persons may submit to the Dockets Management Branch (address above) written or electronic notices of participation and comments for consideration at the hearing by April 23, 2002. To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open following the hearing until June 21, 2002. Persons who wish to provide additional materials for consideration should file these materials with the Dockets Management Branch (see **ADDRESSES**) by June 21, 2002. Two copies of any written comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number at the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

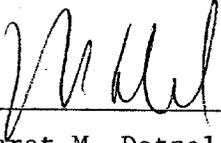
## V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Jones, J. K., D. Fife, S. Curkendall et al., "Coprescribing and Codispensing of Cisapride and Contraindicated Drugs," *Journal of the American Medical Association*, 286:1607-1609, 2001.
  2. Graham, D. J., C. R. Drinkhard, D. Shatin et al., "Liver Enzyme Monitoring in Patients Treated With Troglitazone," *Journal of the American Medical Association*, 286:831-833, 2001.
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3. Smalley, W., D. Shatin, D. K. Wysowski et al., "Contraindicated Use of Cisapride: Impact of Food and Drug Administration Regulatory Action," *Journal of the American Medical Association*, 284: 3036-3039, 2002.

Dated: 4/8/02  
April 8, 2002.



Margaret M. Dotzel,  
Associate Commissioner for Policy

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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Dawn P. Hawkins