

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier D. Hawkins

[Docket No. 2007N-0121]

**Use of Medication Guides to Distribute Drug Risk Information to Patients;  
Public Hearing**

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

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

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**SUMMARY:** The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is announcing a public hearing to obtain feedback on FDA's Medication Guide program, which provides for the distribution of FDA-approved written patient information for certain drug and biological products that pose serious and significant public health concerns. FDA is interested in obtaining public comment on ways to improve communication to patients who receive Medication Guides. The purpose of the public hearing is to solicit information and views from interested persons on specific issues associated with the development, distribution, comprehensibility, and accessibility of Medication Guides, which are required to convey risk information to patients.

*Dates and Times:* The public hearing will be held on June 12 and 13, 2007, from 8:30 a.m. to 4:30 p.m. on both days. Submit written or electronic notices of participation by 4:30 p.m. on May 12, 2007. Written and electronic comments will be accepted until July 12, 2007.

*Location:* 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).

*Addresses:* Submit written or electronic notices of participation to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or on the Internet at <http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm>. Submit written or electronic comments to <http://www.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm> or to the Division of Dockets Management. 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> approximately 21 days after the hearing.

*For Registration to Attend and/or to Participate in the Meeting:* Seating at the meeting is limited. People interested in attending should register at <http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm> or submit a written request for registration to the Division of Dockets Management (see *Addresses*) by 4:30 p.m. on May 12, 2007. Registration is free and will be on a first-come, first-served basis.

If you wish to make an oral presentation during the open session of the meeting, you must state this intention on your notice of participation (see *Addresses*) and provide an abstract of your presentation by May 12, 2007. In the notice, submit your name, title, business affiliation, address, telephone and fax numbers, and e-mail address. FDA has identified questions and subject matter of special interest in section II of this document. You should also identify the subject matter and question number you wish to address in your presentation, and the approximate time requested for your presentation. Individuals and organizations with common interests are urged to consolidate

or coordinate their presentations and to request time for a joint presentation. FDA may require joint presentations by persons with common interests. We will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. You must submit final electronic presentations, if any, to Mary Gross (see *Contacts*) by no later than June 6, 2007.

*Contacts:* Mary C. Gross, Safety Policy and Communication Staff (HFD-001), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5421, e-mail: [mary.gross@fda.hhs.gov](mailto:mary.gross@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

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

FDA is committed to ensuring that prescribers, patients, and their families have the information needed to support the safe and effective use of prescription medications. In the **Federal Register** of December 1, 1998 (63 FR 66378), FDA published its final rule entitled "Prescription Drug Product Labeling; Medication Guide Requirements" (effective June 1, 1999). The final rule included provisions that require the distribution of FDA-approved written patient information, Medication Guides, for certain prescription drug and biological products that pose a serious and significant public health concern (see part 208 (21 CFR part 208)). Medication Guides are intended to provide information that FDA has determined is necessary to patients' safe and effective use of drug products. Under § 208.24, manufacturers who ship drug products for which Medication Guides are required are responsible for ensuring that Medication Guides are provided in sufficient numbers to allow distributors, packers, or authorized dispensers to provide the guides to all

patients who receive the drug product. Alternatively, manufacturers may provide the means for distributors, packers, or authorized dispensers to produce and provide Medication Guides to patients.

Section 208.24 also requires each authorized dispenser of a prescription drug for which a Medication Guide is required to provide the guide to the patient, or to the patient's agent, when the product is dispensed, unless exempt from this requirement under § 208.26. The failure to provide a Medication Guide when such a product is dispensed would cause the product to be misbranded in violation of the Federal Food, Drug, and Cosmetic Act (the act) (see sections 502(a), 201(n), and 503(b)(2) of the act (21 U.S.C. 352(a), 321(n), and 353(b)(2))).

Consumers may receive prescription drug information through sources other than Medication Guides. For example, patient package inserts (PPIs) are FDA-approved patient information required to be dispensed with certain drugs such as estrogens (21 CFR 310.515) and oral contraceptives (21 CFR 310.501) to ensure the safe and effective use of these products. PPIs are considered part of the product labeling. Products with Medication Guides do not have PPIs; a required Medication Guide would replace an existing PPI for a product. Consumer medication information (CMI) is another source of prescription drug information. CMI, which is not FDA-approved, is a private sector initiative based on Public Law 104–180. This law sets specific distribution and quality goals and timeframes for the private sector distribution of written prescription drug information to consumers. The law requires that the Secretary of the Department of Health and Human Services evaluate the private sector progress toward meeting these goals, including that, by 2006, 95 percent of people receiving new prescriptions would receive useful written patient information

with their prescriptions. For this public hearing, FDA is not soliciting comments on PPIs or the CMI initiative. Comments should be limited to the Medication Guide program, including the questions listed in section II of this document.

A list of drug products with Medication Guides is available on FDA's Web site at [http://www.fda.gov/cder/offices/ods/medication\\_guides.htm](http://www.fda.gov/cder/offices/ods/medication_guides.htm).

## **II. Scope of Hearing**

FDA is interested in obtaining public comment on ways to improve communication to patients consistent with the requirement that Medication Guides, FDA-approved patient information, be distributed for selected prescription drugs that pose a serious and significant public health concern. As stated in § 208.1, patient labeling in the form of a Medication Guide is required if one or more of the following circumstances exist:

1. The drug product is one for which patient labeling could help prevent serious adverse effects.

2. The drug product is one that has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect the patients' decision to use, or continue to use, the product.

3. The drug product is important to health and patient adherence to directions for use is crucial to the effectiveness of the drug.

The following questions are organized according to consumers, pharmacies/mail order pharmacies, manufacturers, information vendors/wholesalers, and academicians/researchers. Specifically, we are seeking input on the following issues:

*Consumers*

1. What is the best way for consumers to be informed about the serious risks of a drug product or other important prescribing information? Do Medication Guides have a unique or important role in educating consumers about these risks compared to other written medication information distributed at the pharmacy? Should the information be combined or simplified into fewer or one communication vehicle(s)?

2. How do consumers prefer to receive Medication Guide information (e.g., paper, e-mail, Internet)? When should they receive Medication Guide information (e.g., when prescribed, when dispensed, when they download it from a Web site or e-mail message)?

3. Are Medication Guides easy to read and understand? How can Medication Guides be improved? Do they serve as useful adjuncts to counseling by physicians or pharmacists?

*Pharmacies/Mail Order Pharmacies*

1. Currently, how are you informed that a Medication Guide is required to be distributed with a specific medication?

2. How do you receive Medication Guides from the manufacturers (e.g., in what format)? Should the way you receive these be changed? If so, how?

3. What are the challenges in complying with the Medication Guide regulation, maintaining an adequate supply of Medication Guides, and distributing Medication Guides to consumers? What changes should be made to the Medication Guide program to address these challenges?

4. What steps would you need to take to facilitate electronic distribution of Medication Guides (e.g., e-mailed to patients)?

5. Do you consider the Medication Guide to be a valuable tool in counseling patients about drugs with serious risks?

6. Do Medication Guides have a unique role compared to other communication vehicles that patients receive at the pharmacy? Should the information be combined or simplified into fewer communication vehicles?

7. What process improvements could be made to ensure that patients receive appropriate drug risk information at the pharmacy?

8. What are the advantages and disadvantages of having Medication Guides to cover a class of drugs versus Medication Guides for each individual product in a class?

### *Manufacturers*

1. What steps do you take to ensure compliance with the Medication Guide requirements? What challenges do you encounter in complying with the requirement to distribute Medication Guides with the product to pharmacies and others? How do you ensure that pharmacies are receiving a sufficient supply of Medication Guides?

2. Have means other than paper, such as electronic files, been used to supply Medication Guides to pharmacies or third-party vendors? If so, please describe your experience. If not, please explain why not.

3. How do you instruct pharmacies that Medication Guides must be dispensed with certain prescription drugs per § 208.24(d)?

4. Should standardized language and/or a uniform symbol on the container label be used for the required instruction to dispensers? If so, please propose standardized language and suggest a uniform symbol that might be appropriate.

5. What can be done by means of packaging, such as “unit-of-use,” to ensure that a Medication Guide is shipped with the drug product so that it is distributed with each prescription? What are the advantages and

disadvantages of using unit-of-use packaging for any product that requires a Medication Guide?

6. What are the advantages and disadvantages of developing Medication Guides to cover a class of drugs rather than having a separate Medication Guide for each product in a class?

*Information Vendors/Wholesalers*

1. What challenges or issues regarding distribution of Medication Guides have you encountered? What changes should be made to the Medication Guide program to address these challenges?

2. What challenges do information vendors face when offering electronic versions of Medication Guides in the FDA-approved format? What ideas do you have regarding how Medication Guides could be integrated into other consumer information?

*Academics/Researchers*

1. Please describe any research that is available regarding how often patients receive, read, and/or understand Medication Guides.

2. What research is available about Medication Guide comprehensibility and understandability for the diverse range of health literacy levels or special populations (e.g., elderly, adolescents, non-English speaking)? Please describe your recommendations as to how FDA should modify Medication Guides to more effectively inform a broader audience about drug risk information.

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

The Commissioner of the FDA 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 Division of Dockets Management (see *Addresses*). To ensure timely handling, any outer envelope should be clearly marked with the docket number listed in brackets in the heading of this document along with the statement "FDA Public Hearing: Use of Medication Guides to Distribute Drug Risk Information to Patients." Groups should submit two written copies. Requests to make a presentation 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 under the docket number listed in brackets in the heading of this document.

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 (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.

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

To the extent that the conditions for the hearing, as described in this document, conflict with any provisions set out in part 15, this document 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 and Times*). 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 until July 12, 2007. Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management (see *Addresses*). You should annotate and organize your comments to identify the specific questions to which they refer (see section II of this document). Two copies of any mailed comments are to be submitted, except that individuals may submit one paper 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.

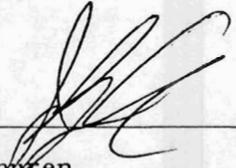
**V. Transcripts**

The hearing will be transcribed as stipulated in § 15.30(b). The transcript of the hearing will be available 30 days after the hearing 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 Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, at a cost of 10 cents per page.

Dated: 4/2/07  
April 2, 2007.



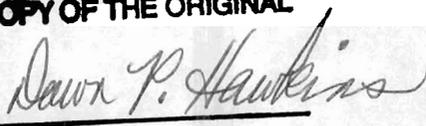
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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