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?

Academicians/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: April 2, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–6506 Filed 4–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0118]

Draft Guidance for Industry on the Content and Format of the Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' This draft guidance is one of a series of guidance documents intended to assist applicants in drafting prescription drug labeling in which prescribing information is clear and accessible and complying with the new requirements in the final rule on the content and format of labeling for prescription drug and biological products (71 FR 3922, January 24, 2006). This draft guidance is intended to help applicants select information for inclusion in the ''Dosage and Administration'' section of labeling and to help them organize that information.

DATES: Submit written or electronic comments on the draft guidance by July 9, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Joseph P. Griffin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4204, Silver Spring, MD 20993–0002, 301–796–1077; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' The draft guidance provides recommendations on how to select information for inclusion in the ''Dosage and Administration'' section of labeling and how to organize information within the section. This draft guidance is one of a series guidances FDA is developing, or has developed, to assist applicants and reviewers with the format and content of certain sections of the labeling for prescription drugs. In the **Federal Register** of January 24, 2006 (71 FR 3998 and 3999), FDA issued final guidances on the format and content of the ''Adverse Reactions'' and ''Clinical Studies'' sections of labeling and draft guidances on implementing the new labeling requirements for prescription drugs and the format and content of the ''Warnings and Precautions,'' ''Contraindications,'' and ''Boxed Warning'' sections of labeling. The new labeling requirements (71 FR 3922) and these guidances are intended to make information in prescription drug labeling easier for health care practitioners to access, read, and use.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, 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.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 201.57 have been approved under OMB control number 0910–0572.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm,* or *http://www.fda.gov/cber/guidelines.htm*.

Dated: March 30, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–6508 Filed 4–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0106]

Draft Guidance for Clinical Investigators, Sponsors, and Investigational Review Boards on Adverse Event Reporting—Improving Human Subject Protection; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Guidance for Clinical Investigators, Sponsors, and IRBs; Adverse Event Reporting—Improving Human Subject Protection.'' This guidance is intended to assist the research community in interpreting requirements for submitting reports of unanticipated problems, including certain adverse events reports, to the Institutional Review Board (IRB). FDA developed this draft guidance in response to concerns raised by the IRB community that increasingly large volumes of individual adverse event reports are inhibiting rather than enhancing IRBs' ability to adequately protect human subjects. The guidance provides recommendations to IRBs, sponsors, and investigators on improving the usefulness of the adverse event information submitted to IRBs.

DATES: Submit written or electronic comments on the draft guidance by June 8, 2007. General comments on agency guidance documents are welcome at any time.