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 collection(s) of information in the draft guidances are estimated in section ''VIII. Paperwork Reduction Act of 1995'' of the final rule entitled ''Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products,'' published elsewhere in this issue of the **Federal Register**.

V. Electronic Access

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

Dated: September 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–543 Filed 1–18–06; 10:28 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2000D–1306 (formerly 00D–1306) and 2001D–0269 (formerly 01D–0269)]

Two Guidances for Industry on the Content and Format 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 two guidances for industry entitled ''Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products—Content and Format'' and ''Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' These guidances are two of a series of guidance documents intended to assist applicants in complying with the new requirements in the final rule on the content and format of labeling for human prescription drug and biological products published elsewhere in this issue of the **Federal Register**.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of these guidances 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 to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidances may also be obtained by calling CBER at 1–800–835–4709 or 301 827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidances 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 guidance documents.

FOR FURTHER INFORMATION CONTACT:

Janet Norden, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., bldg. WO22, rm. 4202, Silver Spring, MD 20993, 301–796–2270, or

Toni Stifano, Center for Biologics Evaluation and Research (HFM–600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6190.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register**of December 22, 2000 (65 FR 81082), FDA published a proposed rule to revise the content and format of prescription drug labeling. The agency's final rule amending the requirements for the content and format of labeling for human prescription drug and biological products is published elsewhere in this issue of the **Federal Register**. The new regulations are designed to make information in prescription drug labeling easier for health care practitioners to access, read, and use, thereby increasing the extent to which practitioners rely on labeling for prescribing decisions. Among other changes, the final rule makes minor content changes and reorders certain sections of labeling, based on the importance of the information to practitioners and the frequency with which practitioners refer to a section.

II. The Guidances

FDA is developing a series of guidances on selected sections of prescription drug labeling, as well as guidance on how to implement the new requirements. This notice announces the availability of two guidance documents, entitled ''Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products—Content and Format'' and ''Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' As described later in this document, these two guidances were previously published for comment.

The guidances are intended to help applicants and reviewers do the following: (1) Select information for inclusion in the ''Adverse Reactions'' and ''Clinical Studies'' sections of prescription drug labeling; (2) characterize information selected for inclusion in these sections; and (3) organize and present the information, including use of graphs and tables, within these sections.

• The guidance entitled ''Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products—Content and Format'' provides recommendations on the ''Adverse Reactions'' section of labeling. In the **Federal Register** of June 21, 2000 (65 FR 38563), FDA published a document announcing the availability of a draft guidance for industry entitled ''Content and Format of the Adverse Reactions Section of Labeling for Human Drugs and Biologics.'' The agency received 14 comments from nine pharmaceutical firms, a trade organization, a pharmacy professional society, a health insurance company, a medical publishing company, and a consumer. In response to these comments, the agency made a number of revisions to the draft guidance. Most significantly, the final guidance makes recommendations on how to make the most clinically important information accessible to health care practitioners. It provides recommendations on how to characterize and organize information and it clarifies the recommended criteria for determining when to include low frequency adverse events in the ''Adverse Reactions'' section.

• The guidance entitled ''Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products—Content and Format'' provides recommendations on the ''Clinical Studies'' section of labeling. In the **Federal Register** of July 9, 2001 (66 FR 35797), FDA published a document announcing the availability of a draft guidance for industry entitled ''Content and Format of the Clinical Studies Section of Labeling for Human Drugs and Biologics.'' The agency received seven comments from six pharmaceutical firms and one trade

organization. In response to these comments, the agency has made revisions to the draft guidance. The final guidance provides several examples of the types of studies that can be included in the ''Clinical Studies'' section. The final guidance also provides clarification on when it is appropriate to include comparative data.

Elsewhere in this issue of the **Federal Register**, the agency is making available for comment draft guidances on implementing the content and format requirements and on the ''Warnings and Precautions,'' ''Contraindications,'' and ''Boxed Warning'' sections of labeling.

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). They represent the agency's current thinking on this topic. They do not confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidances. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should identify clearly which guidance they are commenting on and should be identified with the docket number found in brackets in the heading of this document. The guidances and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Paperwork Reduction Act of 1995

These guidances contain information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collection(s) of information in the guidances are estimated in section ''VIII. Paperwork Reduction Act of 1995'' of the final rule entitled ''Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products,'' published elsewhere in this issue of the **Federal Register**.

V. Electronic Access

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Dated: September 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–544 Filed 1–18–06; 10:29 am]

BILLING CODE 4160–01–S