

submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by May 4, 2009. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 31, 2009. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, 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. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 17, 2009.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

[FR Doc. E9–4374 Filed 3–2–09; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2009–D–0095]

#### **Draft Guidance for Industry on the Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products—Content and Format; Availability**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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.” This draft guidance is one of a series of guidance documents intended to assist applicants in complying with new FDA regulations on the content and format of labeling for human prescription drug and biological products. The draft guidance describes the recommended information to include in the *Clinical pharmacology* section of labeling that pertains to the safe and effective use of

human prescription drug and biological products.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by June 1, 2009.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. The 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.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

#### **FOR FURTHER INFORMATION CONTACT:**

*Regarding the guidance:* Paul Hepp, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1270, Silver Spring, MD 20993–0002, 301–796–1538; or

Lei Zhang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3106, Silver Spring, MD 20993–0002, 301–796–1635; or

Stephen M. 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**

In the **Federal Register** of January 24, 2006 (71 FR 3922), FDA published a final rule entitled “Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products,” to revise the agency’s previous regulations on labeling

(effective June 30, 2006). The new FDA 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 things, the new FDA regulations require that the *Clinical pharmacology* section of the labeling contain the following subsections: *Mechanism of action*, *Pharmacodynamics*, and *Pharmacokinetics* (§ 201.57(c)(13)(i) (21 CFR 201.57(c)(13)(i)).

FDA is announcing the availability of a draft guidance for industry entitled “Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.” The draft guidance is intended to assist applicants in producing the *Clinical pharmacology* section of labeling for human prescription drug and biological products that is consistent, understandable, organized, clinically useful, and in compliance with the new requirements of § 201.57(c)(13)(i). The ultimate goal of the guidance is to optimize patient drug therapy.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on the content and format of the clinical pharmacology section of labeling for human prescription drug and biological products. 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 requirements 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 this document. 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 related to the content and format of labeling have been approved under OMB control no. 0910–0572; the collections of information related to pharmacogenomic data have been approved under OMB control no. 0910–0557.

#### IV. 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.regulations.gov>.

Dated: February 20, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9–4372 Filed 3–2–09; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on

proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Officer on (301) 443–1129.

*Comments are invited on:* (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

#### Proposed Project: HRSA Office of Performance Review (OPR) Leading Practices Data Collection Initiative—NEW

HRSA conducts performance reviews to assure that HRSA-funded grantees are successfully accomplishing their program purposes. While the Office of Performance Review's (OPR) primary function is to conduct performance reviews, another core function is to identify leading practices through the performance review process. The purpose of this submission is to collect qualitative information from diverse grantees across HRSA and identify a program component (activity, strategy, process, or intervention) that has been shown to work effectively, and produce successful outcomes, supported by objective and/or subjective data sources. Some characteristics of the program components that grantees will be asked to describe are their ability to be replicable and adaptable, ability to be documented, and ability to lead to successful program outcomes.

In order to document and evaluate leading practices, grantees with potential leading practices will be asked to complete both the Data Collection Tool and the Narrative. The information collected through these documents will be submitted to OPR. The estimated annual burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Data Collection Tool .....	40	1	40	3	120
Narrative .....	40	1	40	3	120
Total .....					240

E-mail comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: February 24, 2009.

**Alexandra Huttinger,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. E9–4459 Filed 3–2–09; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA

Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

*Proposed Project:* Health Centers Patient Survey—New.

The Health Center program supports Community Health Centers (CHCs), Migrant Health Centers (MHCs), Health Care for the Homeless (HCH) projects, and Public Housing Primary Care (PHPC) programs. Health Centers receive grants from HRSA to provide primary and preventive health care services to medically underserved populations.

The proposed Patient Survey will collect in-depth information about health center patients, their health