

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
310.305(c)(5) .....	3	1	3	1	3
314.80(c)(1)(iii) .....	5	1	5	1	5
314.80(c)(2) .....	665	22.85	15,195	60	911,700
<b>Total</b> .....	.....	.....	.....	.....	<b>911,708</b>

<sup>1</sup> The reporting burden for §§ 310.305(c)(1), (c)(2), and (c)(3), and 314.80(c)(1)(i) and (c)(1)(ii) is reported under OMB control number 0910-0291. The capital costs or operating and maintenance costs associated with this collection of information are approximately \$25,000 annually.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
310.305(f) .....	25	1	25	16	400
314.80(i) .....	665	601.5	399,998	16	6,399,968
<b>Total</b> .....	.....	.....	.....	.....	<b>6,400,368</b>

<sup>1</sup> There are no capital costs or operating costs associated with this collection of information. There are maintenance costs of \$22,000 annually.

These estimates are based on FDA's knowledge of adverse drug experience reporting, including the time needed to prepare the reports, and the number of reports submitted to the Agency.

Dated: March 15, 2012.

**Leslie Kux,**  
Acting Assistant Commissioner for Policy.  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration [Docket No. FDA-2011-N-0883]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by April 19, 2012.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written

comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to *oira\_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0572. Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, *Juanmanuel.Vilela@FDA.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products—(OMB Control Number 0910-0572)—(Extension)

FDA's final rule entitled "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products" (the final rule), which published on January 24, 2006 (71 FR 3922), and was effective on June 30, 2006, amended FDA's regulations governing the format and content of labeling for human prescription drug and biological products to require that the labeling of new and recently approved products contain highlights of prescribing information, a table of contents for prescribing information, reordering of

certain sections, minor content changes, and minimum graphical requirements. These revisions were intended to make it easier for health care practitioners to access, read, and use information in prescription drug labeling; to enhance the safe and effective use of prescription drug products; and to reduce the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information.

#### *A. Summary of Prescription Drug Labeling Content and Format Requirements That Contain Collections of Information*

Section 201.56 (21 CFR 201.56) requires that prescription drug labeling contain certain information in the format specified in either § 201.57 (21 CFR 201.57) or § 201.80 (21 CFR 201.80), depending on when the drug was approved for marketing. Section 201.56(a) sets forth general labeling requirements applicable to all prescription drugs. Section 201.56(b) specifies the categories of new and more recently approved prescription drugs subject to the revised content and format requirements in §§ 201.56(d) and 201.57. Section 201.56(c) sets forth the schedule for implementing these revised content and format requirements. Section 201.56(e) specifies the sections and subsections, required and optional, for the labeling of older prescription drugs not subject to the revised format and content requirements.

Section 201.57(a) requires that prescription drug labeling for new and more recently approved prescription drug products include "Highlights of

Prescribing Information.” Highlights provides a concise extract of the most important information required under § 201.57(c) (the Full Prescribing Information (FPI)), as well as certain additional information important to prescribers. Section 201.57(b) requires a table of contents to prescribing information, entitled “Full Prescribing Information: Contents,” consisting of a list of each heading and subheading along with its identifying number to facilitate health care practitioners’ use of labeling information. Section 201.57(c) specifies the contents of the FPI. Section 201.57(d) mandates the minimum specifications for the format of prescription drug labeling and establishes minimum requirements for key graphic elements such as bold type, bullet points, type size, and spacing.

Older drugs not subject to the revised labeling content and format requirements in § 201.57 remain subject to labeling requirements at § 201.80 (in the final rule, former § 201.57 was redesignated as § 201.80). Section

201.80(f)(2) requires that within 1 year, any FDA-approved patient labeling be referenced in the “Precautions” section of the labeling of older products and either accompany or be reprinted immediately following the labeling.

#### B. Estimates of Reporting Burden

The PRA information collection analysis in the final rule (71 FR 3964–3967) (currently approved under OMB control number 0910–0572) estimated the reporting burden for a multiyear period. We are requesting that OMB extend approval for the information in this collection, as described below that will continue to be submitted to FDA during this multiyear period.

Annual Burden for Prescription Drug Labeling Design, Testing, and Submitting to FDA for New Drug Applications (NDAs) and Biologics License Applications (BLAs) (§§ 201.56 and 201.57) (Table 1)

New drug product applicants must:

(1) Design and create prescription drug

labeling containing Highlights, Contents, and FPI, (2) test the designed labeling (e.g., to ensure that the designed labeling fits into carton-enclosed products), and (3) submit it to FDA for approval. Based on the projected data estimated in the final rule, FDA estimates that it takes applicants approximately 3,349 hours to design, test, and submit prescription drug labeling to FDA as part of an NDA or a BLA under the revised regulations. Approximately 84 applicants submit approximately 105 new applications (NDAs and BLAs) to FDA per year, totaling 351,645 hours.

In the **Federal Register** of December 19, 2011 (76 FR 78668), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED REPORTING BURDEN FOR NEW DRUG APPLICATIONS<sup>1</sup>

Category (21 CFR section)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual Burden for Labeling Requirements in §§ 201.56 and 201.57 .....	84	1.25	105	3,349	351,645
<b>Total .....</b>	.....	.....	.....	.....	<b>351,645</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 15, 2012.

**Leslie Kux,**  
Acting Assistant Commissioner for Policy.  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration [Docket No. FDA–2012–N–0247]

#### Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act Products

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain

information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in the guidance for industry on formal meetings with sponsors and applicants for Prescription Drug User Fee Act (PDUFA) products.

**DATES:** Submit either electronic or written comments on the collection of information by May 21, 2012.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the

docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, [Juanmanuel.vilela@fda.hhs.gov](mailto:Juanmanuel.vilela@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information,