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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0500]

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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 *[insert date 30 days after date of publication in the Federal Register]*.

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: 202-395-6974, or e-mailed 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: Elizabeth Berbakos, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3792.

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 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 3922 at 3964 to 3967) (currently approved under OMB Control Number 0910-0572) estimated the reporting burden for a multi-year period. We are requesting that OMB extend approval for the information in this collection, as described below, which continue to be submitted to FDA during this multi-year 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 BLA under the revised regulations. Approximately 85 applicants submit approximately 107 new applications (NDAs and BLAs) to FDA per year, totaling 358,343 hours.

Burden Associated with Labeling Supplements for Applications Approved Within 5 Years Prior to the Effective Date of the Rule (§ 201.57) (Table 2)

The final rule required that prescription drug applications approved during the 5 years before, or pending on, the effective date conform to format and content requirements at § 201.57. For these products, applicants must redesign and negotiate the labeling, including Highlights and Contents, test the redesigned labeling, and prepare and submit that labeling to FDA for approval. Based on the projected data estimated in the final rule, labeling supplements for a total of approximately 344 innovator products are expected to be submitted to FDA over a 5-year period (beginning in year 3 and ending in year

7 after the effective date of the final rule). Approximately 172 applicants submit these labeling supplements, and the time required for redesigning, testing, and submitting the labeling to FDA is approximately 196 hours per application, totaling 67,424 hours.

Burden Associated with Revised Labeling Efficacy Supplements Submitted on or After the Effective Date of the Rule (§§ 201.56(d) and 201.57) (Table 2)

Efficacy supplemental applications for older drugs submitted to FDA on or after the effective date of the final rule are subject to the content and format requirements of §§ 201.56(d) and 201.57. To meet these requirements, applicants must revise the existing labeling for these products. Each year an increasing number of innovator drug labeling will have been revised, and over time, very few efficacy supplements independently will generate labeling revisions. Based on the projected data estimated in the final rule, the number of affected efficacy supplements over 10 years, beginning with year 3, is 186, with a decreasing number each year over the period. Approximately 172 applicants will trigger approximately 186 efficacy supplements, each one requiring approximately 196 hours to revise the labeling in the application, totaling 36,456 hours. (As stated in the final rule, in addition to this burden, a minimal annual reporting burden (fewer than 7) will continue indefinitely).

Burden Associated with Revised Labeling for Efficacy Supplements for Generic Drug Products (§ 201.57) (Table 2)

Based on the projected data estimated in the final rule, beginning in year 3 and continuing throughout the 10-year period analyzed, approximately 42 generic applicants per year must submit labeling supplements. Approximately 336 already approved generic drug applications must submit labeling supplements over the 10-year period after the effective date of the rule. The time required to revise and submit this labeling to FDA is approximately 27

hours per application, totaling 9,072 hours. (As stated in the final rule, in addition to this burden, a minimal annual reporting burden associated with a very small number of generic applications referencing older drugs may continue indefinitely).

C. Capital Costs

As discussed in the final rule, a small number of carton-enclosed products may require new packaging to accommodate longer inserts. As many as 5 percent of the existing products affected by the final rule (i.e., products with new efficacy supplements, products approved in the 5 years prior to the effective date of the rule, and affected abbreviated new drug applications) may require equipment changes at an estimated cost of \$200,000 each product.

In the **Federal Register** of September 29, 2008 (73 FR 56592), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received relating to the paperwork.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR NEW DRUG APPLICATIONS¹

Category (21 CFR Section)	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours per Response	Total Hours
Annual Burden for Labeling Requirements in §§ 201.56 and 201.57	85	1.26	107	3,349	358,343
Total					358,343

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

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDENS FOR LABELING REVISIONS TO ALREADY-APPROVED DRUG PRODUCTS¹

Category (21 CFR Section)	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours per Response	Total Hours
Burden associated with revised labeling for applications approved within 5 years prior to June 30, 2006 (§ 201.57)	172	2	344	196	67,424
Burden associated with revised labeling for efficacy supplements submitted on or after June 30, 2006 (§§ 201.56(d) and 201.57)	172	1.08	186	196	36,456
Burden associated with revised labeling for efficacy supplements for generic drug products (§ 201.57)	42	8	336	27	9,072
Total					112,952

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

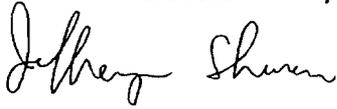
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Dated: _____

December 24, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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