Providers and Systems) Home Health Care Survey. The Home Health Care CAHPS survey, as initially discussed in the May 4, 2007 **Federal Register** (72 FR 25356, 25452), is part of a family of CAHPS® surveys that ask patients about their health care experiences. The Home Health Care CAHPS survey, developed by the Agency for Healthcare Research and Quality (AHRQ), creates a standardized survey for home health patients to assess their home health care providers and the quality of their home health care. Prior to this survey, there was no national standard for collecting such information that would allow comparisons across all home health agencies.

AHRQ conducted a field test to determine the length and content of the Home Health Care CAHPS Survey. CMS has submitted the survey to the National Quality Forum (NQF) for consideration and approval in their consensus process. NQF endorsement represents the consensus opinion of many healthcare providers, consumer groups, professional organizations, purchasers, federal agencies, and research and quality organizations. The final survey has also been submitted to the Office of Management and Budget (OMB) for their approval under the Paperwork Reduction Act (PRA) process.

The survey captures topics such as patients' interactions with the agency, access to care, interactions with home health staff, provider care and communication, and patient characteristics. The survey allows the patient to give an overall rating of the agency, and asks if the patient would recommend the agency to family and friends.

CMS is beginning plans for implementation of Home Health Care CAHPS Survey. Administration of the survey will be conducted by multiple, independent survey vendors working under contract with home health agencies to facilitate data collection and reporting. Recruitment and training of vendors who wish to be approved to collect Home Health Care CAHPS data will begin in 2009. Home health agencies interested in learning about the survey and/or voluntarily participating in the survey are encouraged to view the Home Health Care CAHPS Web site: *http://www.homehealthCAHPS.org*. Information about the project can also be obtained by sending an e-mail to *HHCAHPS@rti.org*.

Home health agency participation in the Home Health Care CAHPS Survey is currently voluntary. *Form Number:* CMS–10275 (OMB# 0938–New); *Frequency:* Semi-annually, once and occasionally; *Affected Public:* Individuals or households; *Number of Respondents:* 2,706,000; *Total Annual Responses:* 2,706,000; *Total Annual Hours:* 541,200.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Application for Prescription Drug Plans (PDP); Application for Medicare Advantage Prescription Drug (MA–PD); Application for Cost Plans to Offer Qualified Prescription Drug Coverage; Application for Employer Group Waiver Plans to Offer Prescription Drug Coverage; Service Area Expansion Application for Prescription Drug Coverage; *Use* Collection of this information is mandated in Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and under supporting regulations Subpart K of 42 CFR 423 entitled ''Application Procedures and Contracts with PDP Sponsors.''

Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA–PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application. The information will be collected under the solicitation of proposals from PDP, MA–PD, Cost Plan, PACE, and EGWP Plan applicants. The collected information will be used by CMS to: (1) Ensure that applicants meet CMS requirements, (2) support the determination of contract awards. *Form Number:* CMS–10137(OMB#: 0938–0936); *Frequency:* Reporting–Once; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 455; *Total Annual Responses:* 455; *Total Annual Hours:* 11,890.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by March 10, 2009:

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: December 30, 2008.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E9–65 Filed 1–8–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0500]

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 February 9, 2009.

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 APPLICATIONS[1]

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

[1]There 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 PRODUCTS[1]

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

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

Dated: December 24, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–175 Filed 1–8–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0657]

Agency Information Collection Activities; Proposed Collection; Comment Request; Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use

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