comments and suggestions submitted within 60 days of this publication.

Dated: September 24, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8–22752 Filed 9–26–08; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Protection and Advacacy (P&A) Voting Access Application and Annual Report.

OMB No.: 0970–0326.

Description: This is a revision to include the application for the previously cleared Help America Vote Act (HAVA) Annual report.

An application is required by Federal statute (the Help America Vote Act (HAVA) of 2002, Pub. L. 107–252, Section 291, Payments for Protection and Advocacy Systems, 42 U.S.C. 15461). Each State Protection & Advocacy (P&A) System must prepare an application in accordance with the program announcement.

There is no application kit; the P&As application may be in the format of its choice. It must, however, be signed by the P&As Executive Director or the designated representative, and contain the assurances as outlined under Part I.C. Use of Funds. The P&As designated representatives may signify their agreement with the conditions/assurances by signing and returning the assurance document Attachment B, found in Part IV of this Instruction. The assurance document signed by the Executive Director of the P&A, or other designated person, should be submitted with the application to the Administration on Developmental Disabilities.

An annual report is required by Federal statute (the Help America Vote Act (HAVA) of 2002, Pub. L. 107–252, Section 291, Payments for Protection and Advocacy Systems, 42 U.S.C. 15461). Each State Protection & Advocacy (P&A) System must prepare and submit an annual report at the end of every fiscal year. The report addresses the activities conducted with the funds provided during the year. The information from the annual report will be aggregated into an annual profile of how HAVA funds have been spent. The report will also provide an overview of the P&A goals and accomplishments and permit the Administration on Developmental Disabilities to track progress to monitor grant activities.

Respondents: Protection & Advocacy Systems—All States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, American Samoa, and Guam.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Protection and Advocacy (P&A) Voting Access Annual Report	55	1	16	880
Protection and Advocacy (P&A) Voting Access Application	55	1	20	1,100

Estimated Total Annual Burden Hours: 1,980.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: September 24, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8–22754 Filed 9–26–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0500]

Agency Information Collection Activities; Proposed Collection; 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 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 provisions of FDA's requirements on content and format of labeling for human prescription drug and biological products.

DATES: Submit written or electronic comments on the collection of information by November 28, 2008.

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: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

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, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 through 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 will 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.

TABLE 1.—ESTIMATED 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 REPORTING BURDENS FOR LABELING REVISIONS TO ALREADY-APPROVED DRUG PRODUCTS[1]

Category (21 CFR Section)	Year(s) In Which Burdens Occur After June 30, 2006	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours per Response	Total Hours	Total Capital Costs
Burden associated with revised labeling for applications approved within 5 years prior to June 30, 2006 (§ 201.57)	Beginning year 3, ending year 7	172	2	344	196	67,424	$3.3 million
Burden associated with revised labeling for efficacy supplements submitted on or after June 30, 2006 (§§ 201.56(d) and 201.57)	Beginning year 3, diminishing over time	172	1.08	186	196	36,456	$2.5 million

TABLE 2.—ESTIMATED REPORTING BURDENS FOR LABELING REVISIONS TO ALREADY-APPROVED DRUG PRODUCTS[1]—Continued

Category (21 CFR Section)	Year(s) In Which Burdens Occur After June 30, 2006	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours per Response	Total Hours	Total Capital Costs
Burden associated with revised labeling for efficacy supplements for generic drug products (§ 201.57)	Beginning year 3, continuing annually thereafter	42	8	336 (for years 1–10)	27	9,072	$2.5 million
Total						112,952	Up to $8.3 million

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

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: September 17, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–22731 Filed 9–26–08; 8:45 am]

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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. 3501 *et seq.*). To request a copy of the clearance requests submitted to OMB for review, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office at (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: Data Collection Tool for State Offices of Rural Health Grant Program: (New)

The mission of the Office of Rural Health Policy (ORHP) is to sustain and improve access to quality care services for rural communities. In its authorizing language (Sec. 711 of the Social Security Act [*42 U.S.C. 912*]), Congress charged ORHP with ''administer[ing] grants, cooperative agreements, and contracts to provide technical assistance and other activities as necessary to support activities related to improving health care in rural areas.''

The State Offices of Rural Health Grant Program (SORH) is authorized by Section 338J of the Public Health Service Act (42 U.S.C. 254r). The purpose of SORH is to assist States in strengthening their rural health care delivery systems by helping to support a focal point for rural health within each State. The program provides funding for an institutional framework that links rural hospitals, providers and communities with State and Federal resources to help develop long term solutions to rural health problems. The average annual award for each State based grantee is $150,000. The law provides for a Federal-State partnership, requiring a State funding match of $3 for each $1 of Federal funding. Over the past 16 years, this program has leveraged in excess of $200 million in State matching funds for rural health.

For SORH, program performance measures were drafted to provide data useful to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993. ORHP seeks to collect information from grantees on their efforts to provide technical assistance to clients within their State. SORH grantees would be required to submit a Technical Assistance Report that includes: 1) The total number of technical assistance encounters provided directly by the grantee; and, 2) the total number of clients that received direct technical assistance from the grantee. Submission of the Technical Assistance Report would be done via e-mail to ORHP no later than 30 days after the end of each twelve month budget period.

The estimated average annual burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Technical Assistance Report	50	1	50	12.5	625
Total	50				625

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Dated: September 22, 2008

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E8–22728 Filed 9–26–08; 8:45 am]

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