

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 Advocacy (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.

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

BILLING CODE 4184-01-P

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