Management and Budget Paperwork Reduction Project. *Fax:* 202–395–6974. *Attn:* Desk Officer for the Administration for Children and Families.

Dated: March 4, 2009.

Brendan C. Kelly,

OPRE Reports Clearance Officer.

[FR Doc. E9–4926 Filed 3–9–09; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Help America Vote Act (HAVA) Voting Access Application and Annual Report.

OMB No.: 0970–0327.

Description: This is a revision to include the application for the previously cleared Help America Vote Act (HAVA) Annual report, Payments to States and Units of Local Government, (42 U.S.C. 15421).

The Help America Vote Act (HAVA) application to States and Units of Local Government is required by Federal statute and regulation. Each State or Unit of Local Government must prepare an application to receive funds under the Help America Vote Act (HAVA), Public Law 107–252, Title II, Subtitle D, Part 2, Sections 261 to 265, Payments to States and Units of Local Government to Assure Access for Individuals with Disabilities (42 U.S.C. 15421–25). The application is provided in writing to the Administration for Children and Families, Administration on Developmental Disabilities.

An annual report is required by Federal statute (the Help America Vote Act (HAVA) of 2002, Public Law 107–252, Section 261, Payments to States and Units of Local Government, 42 U.S.C. 15421). Each State or Unit of Local Government 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 collected from the annual report will be aggregated into an annual profile of how States have utilized the funds and establish best practices for election officials. It will also provide an overview of the State election goals and accomplishments and permit the Administration on Developmental Disabilities to track voting progress to monitor grant activities.

Respondents: Secretaries of State, Directors, State Election Boards, State Chief Election officials.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Help America Vote Act (HAVA) Voting Access Annual Report	50	1	24	1,200
Help America Vote Act (HAVA) Voting Access Application	55	1	50	2,750

Estimated Total Annual Burden Hours: 3,950

Additional Information: Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–6974, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: March 5, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9–4992 Filed 3–9–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0521]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees

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 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 0910–0581. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto,Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

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.

Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees—(OMB Control Number 0910–0581)—Extension

Sponsors are required to monitor studies evaluating new drugs, biologics, and devices (21 CFR 312.50 and 312.56 for drugs and biologics and 21 CFR 812.40 and 812.46 for devices). Various individuals and groups play different roles in clinical trial monitoring. One such group is a Data Monitoring Committee (DMC), appointed by a sponsor to evaluate the accumulating outcome data in some trials. A clinical trial DMC is a group of individuals with pertinent expertise that reviews on a regular basis accumulating data from an ongoing clinical trial. The DMC advises the sponsor regarding the continuing safety of current participants and those yet to be recruited, as well as the continuing validity and scientific merit of the trial.

FDA's guidance document is intended to assist sponsors of clinical trials in determining when a DMC is needed for monitoring a study, and how such committees should operate. The guidance addresses the roles, responsibilities, and operating procedures of DMCs and describes certain reporting and recordkeeping responsibilities, including the following: (1) Sponsor notification to the DMC regarding waivers, (2) DMC reports of meeting minutes to the sponsor, (3) sponsor reports to FDA on DMC recommendations related to safety, (4) standard operating procedures (SOPs) for DMCs, and (5) DMC meeting records.

1. Sponsor Notification to the DMC Regarding Waivers

The sponsor must report to FDA serious unexpected adverse events in drugs and biologics trials (§ 312.32 (21 CFR 312.32)) and unanticipated adverse events in the case of device trials under (§ 812.150(b)(1) (21 CFR 812.150(b)(1))). The agency recommends in the guidance that sponsors notify DMCs about any waivers granted by FDA for expedited reporting of certain serious events.

2. DMC Reports of Meeting Minutes to the Sponsor

The agency recommends in the guidance that the DMC issue a written report to the sponsor based on the DMC meeting minutes. Reports to the sponsor should include only those data generally available to the sponsor. The sponsor may convey the relevant information in this report to other interested parties, such as study investigators. Meeting minutes or other information that include discussion of confidential data would not be provided to the sponsor.

3. Sponsor Reporting to FDA on DMC Recommendations Related to Safety

The requirement of the sponsor to report DMC recommendations related to serious adverse events in an expedited manner in clinical trials of new drugs (§ 312.32(c)) would not apply when the DMC recommendation is related to an excess of events not classifiable as serious. Nevertheless, the agency recommends in the guidance that sponsors inform FDA about all recommendations related to the safety of the investigational product whether or not the adverse event in question meets the definition of ''serious.''

4. SOPs for DMCs

In the guidance, we recommend that sponsors establish procedures to do the following things:

- Assess potential conflicts of interest of proposed DMC members;
- Ensure that those with serious conflicts of interest are not included in the DMC;
- Provide disclosure to all DMC members of any potential conflicts that are not thought to impede objectivity and, thus, would not preclude service on the DMC;
- Identify and disclose any concurrent service of any DMC member on other DMCs of the same, related or competing products;
- Ensure separation, and designate a different statistician to advise on the management of the trial, if the primary study statistician takes on the responsibility for interim analysis and reporting to the DMC; and
- Minimize the risks of bias that arise when the primary study statistician takes on the responsibility for interim analysis and reporting to the DMC, if it appears infeasible or highly impractical for any other statistician to take over responsibilities related to trial management.

5. DMC Meeting Records

The agency recommends in the guidance that the DMC or the group preparing the interim reports to the DMC maintain all meeting records. This information should be submitted to FDA with the clinical study report (§ 314.50(d)(5)(ii) (21 CFR 314.50(d)(5)(ii))).

Description of Respondents: The submission and data collection recommendations described in this document affect sponsors of clinical trials and DMCs.

Burden Estimate: Table 1 of this document provides the burden estimate of the annual reporting burden for the information to be submitted in accordance with the guidance. Table 2 of this document provides the burden estimate of the annual recordkeeping burden for the information to be maintained in accordance with the guidance.

Reporting and Recordkeeping Burdens

Based on information from FDA review divisions, FDA estimates there are approximately 740 clinical trials with DMCs regulated by the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health. FDA estimates that the average length of a clinical trial is 2 years, resulting in an annual estimate of 370 clinical trials. Because FDA has no information on which to project a change in the use of DMCs, FDA estimates that the number of clinical trials with DMCs will not change significantly in the next few years. For purposes of this information collection, FDA estimates that each sponsor is responsible for approximately 10 trials, resulting in an estimated 37 sponsors that are affected by the guidance annually.

Based on information provided to FDA by sponsors that have typically used DMCs for the kinds of studies for which this guidance recommends them, FDA estimates that the majority of sponsors have already prepared SOPs for DMCs, and only a minimum amount of time is necessary to revise or update them for use for other clinical studies. FDA receives very few requests for waivers regarding expedited reporting of certain serious events; therefore, FDA has estimated one respondent per year to account for the rare instance a request may be made. FDA estimates that the DMCs would hold two meetings per year per clinical trial resulting in the issuance of two DMC reports of meeting minutes to the sponsor. One set of both of the meeting records should be maintained per clinical trial. Based on FDA's experience with clinical trials using DMCs, FDA estimates that the sponsor on average would issue two interim reports per clinical trial to the DMC. FDA estimates that the DMCs would hold two meetings per year per clinical trial resulting in the issuance of two DMC reports of meeting minutes to the sponsor. One set of both meeting records should be maintained per clinical trial.

The ''Hours per Response'' and ''Hours per Record'' are based on FDA's experience with comparable recordkeeping and reporting provisions applicable to FDA regulated industry. The ''Hours per Response'' include the time the respondent would spend reviewing, gathering, and preparing the

information to be submitted to the DMC, FDA, or the sponsor. The ''Hours per Record'' include the time to record, gather, and maintain the information.

The information collection provisions in the guidance for §§ 312.30 (21 CFR 312.30), 312.32, 312.38 (21 CFR 312.38), 312.55 (21 CFR 312.55), and 312.56 have been approved under OMB control no. 0910–0014; § 314.50 has been approved under OMB control no. 0910–0001; and §§ 812.35 (21 CFR 812.35) and 812.150 have been approved under OMB control no. 0910–0078.

In the **Federal Register** of October 8, 2008 (73 FR 58970), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of Guidance/Reporting Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
4.4.1.2. Sponsor notification to the DMC regarding waivers	1	1	1	.25	.25
4.4.3.2. DMC reports of meeting minutes to the sponsor	370	2	740	1	740
5. Sponsor reporting to FDA on DMC recommendations related to safety	37	1	37	.5	18.5
Total					758.75

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Recordkeeping Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Hours
4.1. and 6.4 SOPs for DMCs	37	1	37	8	296
4.4.3.2. DMC meeting records	370	1	370	2	740
Total					1,036

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

Dated: March 3, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–4971 Filed 3–9–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0650]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions

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 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 0910–0183. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, 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.

General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions—(OMB Control Number 0910–0183)—Extension

The Administrative Procedures Act (5 U.S.C. 553(e)) provides that every agency shall give an interested person the right to petition for issuance, amendment, or repeal of a rule. Section 10.30 (21 CFR 10.30) sets forth the format and procedures by which an interested person may submit to FDA, in accordance with Sec. 10.20 (21 CFR 10.20) (submission of documents to Division of Dockets Management), a citizen petition requesting the Commissioner of Food and Drugs (the Commissioner) to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. Respondents are individuals or households, State or local governments, not-for-profit institutions and businesses or other for-profit institutions or groups.