

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

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](mailto: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: October 24, 2008.

**Janean Chambers,**

*Reports Clearance Officer.*

[FR Doc. E8-25752 Filed 10-28-08; 8:45 am]

**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2008-D-0030] (formerly Docket No. 2004D-0466)

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**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 the **Federal Register** of April 25, 2008 (73 FR 22423), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0626. The approval expires on August 31, 2011. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: October 22, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8-25791 Filed 10-28-08; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2008-N-0543]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Waiver of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles**

**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 waiver requirement procedures that are recommended by the agency for in vivo demonstration of bioequivalence for generic soluble powder oral dosage form products and Type A medicated articles.

**DATES:** Submit written or electronic comments on the collection of information by December 29, 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:** Denver Presley, Jr., Office of Information Management (HFA-710), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

**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.

**Waiver of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles—21 CFR Part 514 (OMB Control Number 0910-0575)—Extension**

The Center for Veterinary Medicine has written this guidance to address a perceived need for agency guidance in its work with the animal health industry. This guidance describes the procedures that the agency recommends for the review of requests for waiver of in vivo demonstration of bioequivalence for generic soluble powder oral dosage form products and Type A medicated articles.

The Generic Animal Drug and Patent Term Registration Act of 1988 permitted the generic drug manufacturers to copy those pioneer drug products that were no longer subject to patent or other marketing exclusivity protection. The approval for marketing these generic products is based, in part, upon a demonstration of bioequivalence between the generic product and the pioneer product. This guidance clarifies circumstances under which FDA believes the demonstration of bioequivalence required by the statute does not need to be established on the basis of in vivo studies for soluble powder oral dosage form products and

Type A medicated articles. The data submitted in support of the waiver request are necessary to validate the waiver decision.

The requirement to establish bioequivalence through in vivo studies (blood level bioequivalence or clinical endpoint bioequivalence) may be waived for soluble powder oral dosage form products or Type A medicated articles in either of two alternative ways. A biowaiver may be granted if it can be shown that the generic soluble powder oral dosage form product or Type A medicated article contains the same active and inactive ingredient(s) and is produced using the same manufacturing processes as the approved comparator product or article. Alternatively, a biowaiver may be granted without direct comparison to the pioneer product's formulation and manufacturing process if it can be shown that the active pharmaceutical ingredient(s) (API) is the same as the pioneer product, is soluble, and that there are no ingredients in the formulation likely to cause adverse pharmacologic effects. For the purpose of evaluating soluble powder oral dosage form products and Type A medicated articles, solubility can be demonstrated in one of two ways: (1) "USP definition" approach, or (2) "Dosage adjusted" approach.

The respondents for this collection of information are pharmaceutical companies manufacturing animal drugs.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR WATER SOLUBLE POWDERS<sup>1</sup>

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Same formulation/manufacturing process approach	1	1	1	5	5
Same API/ solubility approach	5	5	5	10	50
Total burden hours					55

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN FOR TYPE A MEDICATED ARTICLES<sup>1</sup>

	No. of Respondents	Annual Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
Same formulation/manufacturing process approach	2	2	2	5	10
Same API/ solubility approach	10	10	10	20	200
Total burden hours					210

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

The sources of the previous data are records of generic drug applications over the past 10 years.

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: October 22, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8-25741 Filed 10-28-08; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2008-N-0043]

[FDA No. 225-07-1000]

**Memorandum of Understanding With the National Heart, Lung, and Blood Institute, a Part of the National Institutes of Health**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA's Center for Biologics Evaluation and Research (CBER) and the National Heart, Lung, and Blood Institute (NHLBI), a part of the National Institutes of Health (NIH). This MOU outlines the terms of collaboration between CBER and NHLBI in areas of mutual concern for protecting and improving the public health. Specifically this MOU provides for the implementation of a plan for promoting better communication and understanding of regulations, policies, and statutory responsibilities, and to serve as a forum for discussion of

scientific and clinical topics, questions, and problems that may arise. This MOU also provides the framework for sharing of information.

**DATES:** The agreement became effective September 11, 2008.

**FOR FURTHER INFORMATION CONTACT:**

Keith Wonnacott, Cellular Therapy Branch (HFM-720), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-5102; or John W. Thomas, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute MSC 7950, 6701 Rockledge Dr., Rockledge II, rm. 9150, Bethesda, MD 20892-7950, 301-435-0065.

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: October 15, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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