ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Plan (OCSE–100)	54	8	.5	216
State Plan Transmittal (OCSE–21–U4)	54	8	.25	108

Estimated Total Annual Burden Hours: 324.

SUPPLEMENTARY 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: August 15, 2007.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 07–4081 Filed 8–20–07; 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: Low Income Home Energy Assistance Program (LIHEAP) Grantee Survey.

OMB No.: 0970–0076.

Description: The LIHEAP Grantee Survey is an annual data collection activity, which is sent to grantees of the 50 states and the District of Columbia administering the Low Income Home Energy Assistance Program (LIHEAP). The survey is mandatory in order that national estimates of the sources and uses of LIHEAP funds can be calculated in a timely manner; a range can be calculated of State average LIHEAP benefits; and maximum income cutoffs for four-person households can be obtained for estimating the number of low-income households that are income eligible for LIHEAP under the State income standards.

The need for the above information is to provide the Administration and Congress with fiscal estimates in time for hearings about LIHEAP appropriations and program performance. The information also is included in the Department's annual LIHEAP Report to Congress. Survey information also will be posted on the Office of Community Services' LIHEAP website for access by grantees and other interested parties.

Respondents: 50 States and the District of Columbia.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
LIHEAP Grantee Survey	51	1	3.5	178.50

Estimated Total Annual Burden Hours: 178.50.

SUPPLEMENTARY 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: August 15, 2007.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 07–4082 Filed 8–20–07; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0317]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Pharmacogenomic Data Submissions; Extension

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 resulting from recommendations to sponsors submitting or holding investigational new drugs (INDs), new drug applications (NDAs), or biologic licensing applications (BLAs) on what pharmacogenomic data should be submitted to the agency during the drug development process.

DATES: Submit written or electronic comments on the collection of information by October 22, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments* or *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 the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Guidance for Industry on Pharmacogenomic Data Submissions (OMB Control Number 0910–0557—Extension)

The guidance provides recommendations to sponsors submitting or holding INDs, NDAs, or BLAs on what pharmacogenomic data should be submitted to the agency during the drug development process. Sponsors holding and applicants submitting INDs, NDAs, or BLAs are subject to FDA requirements for submitting to the agency data relevant to drug safety and efficacy (§§ 312.22, 312.23, 312.31, 312.33, 314.50, 314.81, 601.2, and 601.12).

Description of Respondents: Sponsors submitting or holding INDs, NDAs, or BLAs for human drugs and biologics.

Burden Estimate: The guidance interprets FDA regulations for IND, NDA, or BLA submissions, clarifying when the regulations require pharmacogenomics data to be submitted and when the submission of such data is voluntary. The pharmacogenomic data submissions described in the guidance that are required to be submitted to an IND, NDA, BLA, or annual report are covered by the information collection requirements under parts 312, 314, and 601 (21 CFR parts 312, 314, and 601) and are approved by OMB under control numbers 0910–0014 (part 312—INDs); 0910–0001 (part 314—NDAs and annual reports); and 0910–0338 (part 601—BLAs).

The guidance distinguishes between pharmacogenomic tests that may be considered valid biomarkers appropriate for regulatory decisionmaking, and other, less well developed exploratory tests. The submission of exploratory pharmacogenomic data is not required under the regulations, although the agency encourages the voluntary submission of such data.

The guidance describes the voluntary genomic data submission (VGDS) that can be used for such a voluntary submission. The guidance does not recommend a specific format for the VGDS, except that such a voluntary submission be designated as a VGDS. The data submitted in a VGDS and the level of detail should be sufficient for FDA to be able to interpret the information and independently analyze the data, verify results, and explore possible genotype-phenotype correlations across studies. FDA does not want the VGDS to be overly burdensome and time-consuming for the sponsor.

FDA has estimated the burden of preparing a voluntary submission described in the guidance that should be designated as a VGDS. Based on FDA's experience with this guidance over the past few years, and on FDA's familiarity with sponsors' interest in submitting pharmacogenomic data during the drug development process, FDA estimates that approximately 8 sponsors will submit approximately 10 VGDSs and that, on average, each VGDS will take approximately 50 hours to prepare and submit to FDA.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Voluntary Genomic Data Submissions	8	1.25	10	50	500

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

Dated: August 15, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–16470 Filed 8–20–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Devices 101: An Educational Forum; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Regional Office (SWRO), in cosponsorship with the FDA Medical Device Industry Coalition (FMDIC), is announcing a public workshop entitled ''Medical Devices 101: An Educational Forum.'' This public workshop, presented previously on February 9, 2007, is intended to provide an overview on FDA's medical device requirements to entrepreneurs, startup companies, and small businesses.

Date and Time: The public workshop will be held on October 26, 2007, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the FDA SWRO, 4040 North Central Expressway, 9th floor conference room, Dallas, TX.

Contact Person: David Arvelo, Food and Drug Administration, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214–253–4952, FAX: 214–253–4970, e-mail: *oraswrsbr@fda.hhs.gov*.

Registration: FMDIC has a $75 early registration fee. The early registration fee for government officials is $50 and for students is $25 with positive identification. Early registration ends October 12, 2007. After October 12, 2007, registration is $100 for the public at large, $75 for government officials, and $50 for students with positive identification. To register online, please visit *http://www.fmdic.org/*. As an alternative, you may mail your registration information including name, title, organization or company name, physical address, telephone and fax numbers, and e-mail address, along with a check or money order for the appropriate amount payable to the FMDIC, to William Hyman, Texas A&M University, Department of Biomedical Engineering, 3120 TAMU, College Station, TX 75843–3120. The available space will be filled in order of receipt of registration with appropriate fees. Seats are very limited; please submit registration as soon as possible. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site may be available based on space availability on the day of the public workshop beginning at 8 a.m. The cost of registration at the site is $99 payable to FMDIC. The registration fee will be used to offset expenses associated with this event including lunch, refreshments, and course materials.

If you require special accommodations due to a disability, please contact David Arvelo (see *Contact Person*) at least 21 days in advance.

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop. Course handouts may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at an estimated cost of 10 cents per page.

SUPPLEMENTARY INFORMATION: The workshop, previously presented on February 9, 2007 (72 FR 968, January 9, 2007), is being held in response to the interest in the topics discussed from small medical device entrepreneurs and startup manufacturers in the Dallas District area. FDA presents this workshop in cosponsorship with FMDIC to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is also consistent with the purposes of FDA's Regional Small Business Program, which are in part to respond to industry inquiries, develop educational materials, and sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), as an outreach activity by Government agencies to small businesses.

The goal of the workshop is to present information that will enable manufacturers and regulated industry to better comply with the Medical Device Quality System Regulation. The following topics will be broadly covered at the workshop: (1) Medical device classification; (2) establishment registration; (3) device listing; (4) premarket notification; (5) premarket approval; (6) quality system regulation; (7) labeling; (8) recalls, removals, and corrections; (9) medical device reporting; (10) tracking; and (11) postmarket surveillance.

Dated: August 15, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–16375 Filed 8–20–07; 8:45 am]

BILLING CODE 4160–01–S

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, 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, call the HRSA Reports Clearance Office on (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 the Black Lung Clinics Program: (OMB No. 0915–0292) Revision

The Office of Rural Health Policy (ORHP), Health Resources and Services Administration, conducts an annual data collection of user information for the Black Lung Clinics Program. The purpose of the Black Lung Clinics Program is to improve the health status of coal workers by providing services to minimize the effects of respiratory and pulmonary impairments of coal miners. Grantees provide specific diagnostic and treatment procedures required in the management of problems associated with black lung disease which improves the quality of life of the miner and reduces economic costs associated with morbidity and mortality arising from pulmonary diseases. The purpose of collecting this data is to provide HRSA with information on how well each grantee is meeting the needs of active and retired miners in the funded communities.

Data from the annual report will provide quantitative information about