States	Estimated state median income for a four-person family[1]	60 Percent of estimated state median income for a four-person family[2 3]
Missouri	66,939	40,163
Montana	62,353	37,412
Nebraska	69,854	41,912
Nevada	68,646	41,188
New Hampshire	88,625	53,175
New Jersey	97,326	58,396
New Mexico	53,041	31,825
New York	78,061	46,837
North Carolina	64,591	38,755
North Dakota	67,183	40,310
Ohio	71,063	42,638
Oklahoma	57,247	34,348
Oregon	67,605	40,563
Pennsylvania	75,161	45,097
Rhode Island	83,241	49,945
South Carolina	61,494	36,896
South Dakota	64,930	38,958
Tennessee	61,581	36,949
Texas	62,358	37,415
Utah	65,460	39,276
Vermont	73,550	44,130
Virginia	81,919	49,151
Washington	77,676	46,606
West Virginia	56,430	33,858
Wisconsin	75,111	45,067
Wyoming	72,788	43,673

Note: FFY 2010 covers the period of October 1, 2009, through September 30, 2010. The estimated median income for a four-person family living in the United States for this period is $72,336. These estimates become effective for LIHEAP at any time between the date of this publication and October 1, 2009, or the beginning of a LIHEAP grantee's fiscal year, whichever is later.

[1] Prepared by the U.S. Census Bureau, U.S. Department of Commerce (Census Bureau), from an average of data from the 2005, 2006 and 2007 American Community Surveys (ACSs). These estimates, like those derived from any survey, are subject to two types of errors: (1) Non-sampling Error, which consists of random errors that increase the variability of the data and non-random errors that consistently direct the data into a specific direction; and (2) Sampling Error, which consists of the error that arises from the use of probability sampling to create the sample.

[2] These figures were calculated by the U.S. Department of Health and Human Services, Administration for Children and Families, Office of Community Services, Division of Energy Assistance (DEA) by multiplying the estimated State median income for a four-person family for each State by 60 percent.

[3] To adjust for different sizes of family, 45 CFR 96.85 calls for multiplying 60 percent of a State's estimated median income for a four-person family by the following percentages: 52 percent for one person, 68 percent for two persons, 84 percent for three persons, 100 percent for four persons, 116 percent for five persons, and 132 percent for six persons. For each additional family member above six persons, 45 CFR 96.85 calls for adding 3 percentage points to the percentage for a six-person family (132 percent) and multiply the new percentage by 60 percent of a State's estimated median income for a four-person family.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0633]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarketing Adverse Drug Experience Reporting

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 13, 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 0910–0230. Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Postmarketing Adverse Drug Experience Reporting (OMB Control Number 0910–0230—Extension)

Sections 201, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 352, 355, and 371) require that marketed drugs be safe and effective. In order to know whether drugs that are not safe and effective are on the market, FDA must be promptly informed of adverse experiences occasioned by the use of marketed drugs. In order to help ensure this, FDA issued regulations at §§ 310.305 and 314.80 (21 CFR 310.305 and 314.80) to impose reporting and recordkeeping requirements on the drug industry that would enable FDA to take the action

necessary to protect the public health from adverse drug experiences.

All applicants who have received marketing approval of drug products are required to report to FDA serious, unexpected adverse drug experiences, as well as followup reports when needed (§ 314.80(c)(1)). This includes reports of all foreign or domestic adverse experiences as well as those based on information from applicable scientific literature and certain reports from postmarketing studies. Section 314.80(c)(1)(iii) pertains to such reports submitted by non-applicants. Under § 314.80(c)(2), applicants must provide periodic reports of adverse drug experiences. A periodic report includes, for the reporting interval, reports of serious, expected adverse drug experiences and all nonserious adverse drug experiences and an index of these reports, a narrative summary and analysis of adverse drug experiences and a history of actions taken because of adverse drug experiences. Under § 314.80(i), applicants must keep records of all adverse drug experience reports known to the applicant for 10 years.

For marketed prescription drug products without approved new drug applications or abbreviated new drug applications, manufacturers, packers, and distributors are required to report to FDA serious, unexpected adverse drug experiences as well as followup reports when needed (§ 310.305(c)). Section 310.305(c)(5) pertains to the submission of followup reports to reports forwarded by FDA. Under § 310.305(f), each manufacturer, packer, and distributor shall maintain for 10 years records of all adverse drug experiences required to be reported.

The primary purpose of FDA's adverse drug experience reporting system is to provide a signal for potentially serious safety problems with marketed drugs. Although premarket testing discloses a general safety profile of a new drug's comparatively common adverse effects, the larger and more diverse patient populations exposed to the marketed drug provide the opportunity to collect information on rare, latent, and long-term effects. Signals are obtained from a variety of sources, including reports from patients, treating physicians, foreign regulatory agencies, and clinical investigators. Information derived from the adverse drug experience reporting system contributes directly to increased public health protection because the information enables FDA to make important changes to the product's labeling (such as adding a new warning), decisions about risk evaluation and mitigation strategies or the need for postmarket studies or clinical trials, and when necessary, to initiate removal of a drug from the market.

Respondents to this collection of information are manufacturers, packers, distributors, and applicants.

In the **Federal Register** of December 16, 2008 (73 FR 76358), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received on the information collection.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
310.305(c)(5)	1	1	1	1	1
314.80(c)(1)(iii)	5	1	5	1	5
314.80(c)(2)	642	17.88	11,478	60	688,680
Total					688,686

[1] The reporting burden for §§ 310.305(c)(1), (c)(2), and (c)(3), and 314.80(c)(1)(i) and (c)(1)(ii) was reported under OMB control no. 0910–0291. The capital costs or operating and maintenance costs associated with this collection of information are approximately $25,000 annually.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
310.305(f)	25	1	25	16	400
314.80(i)	642	623	400,000	16	6,400,000
Total					7,088,680

[1] There are no capital costs or operating costs associated with this collection of information. There are maintenance costs of $22,000 annually.

Dated: March 6, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA–2009–N–0667]
[FDA 225–07–8006]

Memorandum of Understanding With Baylor College of Medicine, The University of Texas M.D. Anderson Cancer Center, Rice University, University of Houston, The University of Texas Health Science Center at Houston, Texas A&M Health Science Center, The University of Texas Medical Branch at Galveston, and The Methodist Hospital Research Institute for the FDA-ANH Nanotechnology Initiative

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) with The Alliance for NanoHealth (ANH), a collaboration among: Baylor College of Medicine, The University of Texas M.D. Anderson Cancer Center, Rice University, University of Houston, The University of Texas Health Science Center at Houston, Texas A&M Health Science Center, The University of Texas Medical Branch at Galveston, and The Methodist Hospital Research Institute. This MOU identifies the terms of collaboration between FDA and ANH in the area of nanotechnology. Specifically, this MOU establishes the FDA-ANH Nanotechnology Initiative (FANTI), a public-private partnership dedicated to the identification of scientific and translational gaps in moving nanoengineered medical products from the preclinical stages of development through clinical stages and then to commercialization, all with immediate benefit to public health. The activities are aligned with the mutual interests and respective missions of the Parties, including the FDA's Critical Path Initiative which seeks to modernize the product development and regulatory sciences needed to reduce uncertainties about product performance throughout the product life cycle. Thus, a key goal for the Parties is to improve the safety and efficacy of nanoengineered products and speed their delivery to the patients who need them and the consumers who use them.

DATES: The agreement became effective February 11, 2009.

FOR FURTHER INFORMATION CONTACT: Wendy R. Sanhai, Office of the Commissioner (HZ–1), Food and Drug Administration, 5600 Fishers Lane, suite 6A–08, Rockville, MD 20857, 301–827–7867.

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: March 4, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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