ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
LIHEAP Leveraging Report	70	1	38	2,660

Estimated Total Annual Burden Hours: 2,660.

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: February 19, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9–3859 Filed 2–23–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Educational Development and Partnership Division, Office of Head Start

AGENCY: Educational Development and Partnership Division (EDPD), Office of Head Start (OHS), Administration for Children and Families (ACF), Department of Health and Human Services (DHHS).

ACTION: Notice to award a Non-competitive Successor Grant.

CFDA#: 93.600.

Legislative Authority: Section 648(g) of the Head Start Act (42 U.S.C. 9843) for these Career Advancement Partnership Programs.

Project Period: January 22, 2009–September 29, 2009.

SUMMARY: Notice is hereby given that the Administration for Children and Families (ACF), Educational Development and Partnership Division (EDPD) will award a non-competitive successor award to Southwestern Indian Polytechnic Institute (SIPI) a Tribal College federally charted and operated by the Bureau of Indian Education, Department of the Interior located in Albuquerque, NM. Southwestern Indian Polytechnic Institute (SIPI) will assume a grant award under the Head Start Career Advancement Partnership Program for the remainder of the project period January 22, 2009 to September 29, 2009. The Board of Regents, Southwestern Indian Polytechnic Institute, has relinquished the grant to its Federal entity to ensure greater internal controls.

FOR FURTHER INFORMATION CONTACT: Georgeline Sparks, Program Officer, Educational Development and Partnership Division, 1250 Maryland Ave., SW., Washington, DC 20024 or by phone at (202) 205–8539, or by e-mail at *georgeline.sparks@acf.hhs.gov*.

Dated: February 13, 2009.

Patricia Brown,

Acting Director, Office of Head Start.

[FR Doc. E9–3833 Filed 2–23–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0209] (formerly Docket No. 2007D–0491)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Dietary Supplement Labeling Requirements and Recommendations under the Dietary Supplement and Nonprescription Drug Consumer Protection Act

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. Elsewhere in this issue of the **Federal Register**, FDA is announcing that a proposed collection of information regarding labeling requirements for nonprescription human drugs marketed without an approved application has been submitted to OMB for review.

DATES: Fax written comments on the collection of information by March 26, 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–NEW and title, ''Dietary Supplement Labeling Requirements and Recommendations under the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' 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.

Dietary Supplement Labeling Requirements and Recommendations under the Dietary Supplement and Nonprescription Drug Consumer Protection Act

On December 22, 2006, the President signed into law the Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNDCPA) (Public Law 109–462, 120 Stat. 3469). This law amends the Federal Food, Drug, and Cosmetic Act (the act) with respect to serious adverse event reporting for dietary supplements and nonprescription drugs marketed without an approved application. The law also amended the act to add section 403(y) (21 U.S.C. 343(y)), which requires the label of a dietary supplement marketed in the United States to include a domestic address or domestic telephone number through which the product's manufacturer, packer or distributor may receive a report of a serious adverse event associated with the dietary supplement.

In the **Federal Register** of January 2, 2008 (73 FR 197), FDA announced the availability of a draft guidance document entitled ''Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act. '' In the **Federal Register** of December 11, 2008 (73 FR 75438), FDA announced the availability of a revised version of the same draft guidance document . The guidance document contains questions and answers relating to the labeling requirements in section 403(y) of the act and provides guidance to industry on the following topics: (1) The meaning of ''domestic address'' for purposes of the labeling requirements of section 403(y) of the act; (2) FDA's recommendation for the use of an introductory statement before the domestic address or telephone number that is required to appear on the product label under section 403(y) of the act; and (3) FDA's intent regarding enforcing the labeling requirements of section 403(y) of the act.

In the **Federal Register** of January 2, 2008 (73 FR 197), FDA published a notice of availability for the original draft guidance that also gave notice of the proposed collections of information in the draft guidance, included an analysis and burden estimate for these proposed collections of information, and provided 60 days for public comment under the Paperwork Reduction Act of 1995 (PRA). FDA did not revise the PRA burden analysis and estimate when it issued the revised draft guidance in December 2008 because the revisions did not affect them.

Several comments suggested that FDA underestimated the number of dietary supplement labels that would have to be revised. Two comments noted that in the past FDA had estimated the number of distinct dietary supplement labels at 29,514, and another comment noted that in the past FDA had estimated the number of distinct dietary supplement labels at 75,000. Several other comments suggested that the number of dietary supplements sold in the United States was between 50,000 and 60,000 products based on information from the Office of Dietary Supplements at the National Institutes of Health (NIH). All the aforementioned comments suggested that the costs associated with re-labeling the dietary supplements represented a significant burden to the industry. Based on these comments, FDA has revised its estimate of the number of labels that would have to be redesigned to include the complete domestic address or domestic telephone number of the responsible person for each dietary supplement stockkeeping unit (SKU).

FDA used A.C. Nielsen Sales Scanner Data from 2004 to improve its estimate of the number of dietary supplement SKUs. The 2004 A.C. Nielsen scanner data are more recent and more complete than the data FDA used to derive the estimate used in the 60-day notice. FDA also adjusted the Nielsen scanner data estimate to account for methods of sale not covered by the Nielsen scanner data, such as non-participating retailers and internet sales. Based on the adjusted Nielsen scanner data, FDA estimates that the number of dietary supplement SKUs for which sales of the products are greater than zero is 55,600. This number of SKUs is similar to the number of dietary supplement products that was suggested by several comments and the number estimated by the Office of Dietary Supplements at NIH.

FDA did not receive any comments regarding the number of firms that would be responsible for re-labeling the dietary supplement products. Therefore, we retain our estimate that there are about 1,460 dietary supplement firms that must comply with the labeling requirements of section 403(y) of the act. Assuming the 55,600 SKUs are split equally among the firms, then each firm would be responsible for updating about 38 SKUs. FDA also did not receive any comments regarding how many of the dietary supplement SKUs would have to undergo a label change to include the complete domestic address or domestic phone number of the responsible person as required by the DSNDCPA. Thus, as in the 60-day notice, FDA is assuming conservatively that all labels will need to be redesigned.

Several comments noted that the overall process of changing a label requires a significant amount of time to implement; however, FDA did not receive any estimates of the actual time it would take to assess the current layout of each label and redesign it. FDA also did not receive any estimates of how many firms would choose to include an explanatory statement on the reason for the domestic address or telephone number appearing on the label of the dietary supplement product, though several comments speculated that all or nearly all firms would be likely to include an explanatory statement. Because we did not receive any comments on the burden associated with each of these tasks, we retain our original estimates. We assume conservatively that all firms will include an explanatory statement on the label, and we estimate that the redesign of each label to include the domestic address or telephone number and the explanatory statement will take a total of 8 hours (4 hours for each change).

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

Hour Burden Estimate

TABLE 1.—ESTIMATED ONE-TIME REPORTING BURDEN [1]

	No. of Respondents	Annual Frequency per Response	Total annual Responses	Hours Per Response	Total Hours
Domestic address or telephone number labeling requirement (21 U.S.C. 343(y))	1,460	38.0822	55,600	4	222,400
FDA recommendation for label statement explaining purpose of domestic address or telephone number	1,460	38.0822	55,600	4	222,400
Total					444,800

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

Dated: February 17, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–3916 Filed 2–23–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0429] (formerly Docket No. 2007D–0496)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers

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 (the PRA). Elsewhere in this issue of the **Federal Register**, FDA is announcing that a proposed collection of information regarding dietary supplement labeling requirements and recommendations has been submitted for OMB review.

DATES: Fax written comments on the collection of information by March 26, 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 title ''Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers.'' 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.

Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers

On December 22, 2006, the President signed into law the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109–462, 120 Stat. 3469). This law amends the Federal Food, Drug, and Cosmetic Act (the act) with respect to serious adverse event reporting for dietary supplements and nonprescription drugs marketed without an approved application.

Section 502(x) of the act (21 U.S.C. 352(x)), which was added by Public Law 109–462, requires the label of a nonprescription drug product marketed without an approved application in the United States to include a domestic address or domestic telephone number through which a responsible person may receive a report of a serious adverse event associated with the product. In the **Federal Register** of January 2, 2008 (73 FR 196), FDA announced the availability of a draft guidance document entitled ''Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' In the **Federal Register** of December 11, 2008 (73 FR 75436), FDA published a notice of availability of a revised version of the same draft guidance document. The guidance document contains questions and answers relating to the labeling requirement and provides guidance to industry on the following topics: (1) The meaning of ''domestic address'' for purposes of the labeling requirements of section 502(x) of the act; (2) FDA's recommendation for the use of an introductory statement before the domestic address or telephone number that is required to appear on the product label under section 502(x) of the act; and (3) FDA's intent regarding enforcing the labeling requirements of section 502(x) of the act.

Title: Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers.

Description of Respondents: Respondents to this collection of information are manufacturers, packers, and distributors whose name (under section 502(b)(1) of the act (21 U.S.C. 352(b)(1))) appears on the label of a nonprescription drug product marketed in the United States without an approved application.

Burden Estimate: FDA is requesting public comment on the estimated one-time reporting burden from these respondents, as required by 502(x) of the act and described in the guidance ''Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by