

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of hospitals	Total burden hours	Average hourly wage rate*	Total cost burden
Focus groups at intervention sites	6	36	\$57.38	\$2,066
Focus groups at control sites	5	23	57.38	1,320
ASP Questionnaire	11	180	64.73	11,651
Total	22	239	n/a	15,037

* The hourly wage for the focus groups is based upon the mean of the average wages for physicians (\$79.33), pharmacists (\$50.13), and medical and health services managers (\$42.67). The hourly wage for the surveys is based upon the average wages for physicians (\$79.33) and pharmacists (\$50.13). These data come from the May 2008 National Occupational Employment and Wage Estimates, United States,—U.S.

Bureau of Labor Statistics Division of Occupational Employment Statistics, May 2008, National Occupational Employment and Wage Estimates, http://www.bls.gov/oes/2008/may/oes_nat.htm#11-0000.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the annualized and total cost to the federal government for

this two year research project. Project Management includes activities related to coordination between BUSPH staff, contracted staff at MMC and GNYIIA, and monthly phone calls with the task order officer. Project development covers steps taken to revise the research plan and begin implementation. The total cost is estimated to be \$999,995.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST TO THE GOVERNMENT

Cost component	Annualized cost	Total cost
Project Management	\$28,315	\$56,629
Project Development	84,944	169,400
Data Collection and Analysis	169,888	339,776
Technical Assistance and Consultation	60,750	121,500
Confirmatory lab testing	20,000	40,000
Travel	7,500	15,000
Project Supplies and materials	2,450	4,900
Overhead	126,395	252,790
Total	499,998	999,995

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: September 17, 2010.

Carolyn M. Clancy,

Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2010-N-0374]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Petition to Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

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 November 1, 2010.

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: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0608. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

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.

Petition to Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements—(OMB Control Number 0910–0608)—Extension

On October 25, 1994, the Dietary Supplement Health and Education Act (DSHEA) (Public Law 103–417) was signed into law. DSHEA, among other things, amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 402(g) of the FD&C Act (21 U.S.C. 342(g)). Section 402(g)(2) of the FD&C Act provides, in part, that the Secretary of Health and Human Services (the Secretary) may, by regulation, prescribe good manufacturing practices for dietary supplements. Section 402(g)(1) of the FD&C Act states that a dietary supplement is adulterated if “it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations.” Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA may issue regulations necessary for the efficient enforcement of the FD&C Act.

FDA published a final rule on June 25, 2007 (72 FR 34752) (the final rule) that established, in part 111 (21 CFR part 111), the minimum Current Good Manufacturing Practice (CGMP) necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement. On June 25, 2007 (72 FR 34959), FDA

also published an Interim Final Rule (the IFR) establishing a procedure for a petition to request an exemption from 100 percent identity testing of dietary ingredients. The IFR redesignated § 111.75(a)(1) of the CGMP final rule as § 111.75(a)(1)(i) and set forth a procedure for submission of a petition to FDA in a new § 111.75(a)(1)(ii), under which manufacturers may request an exemption from the requirements set forth in § 111.75(a)(1)(i) when the dietary ingredient is obtained from one or more suppliers identified in the petition. The regulation clarifies that FDA is willing to consider, on a case-by-case basis, a manufacturer’s conclusion, supported by appropriate data and information in the petition submission, that it has developed a system that it would implement as a sound, consistent means of establishing, with no material diminution of assurance compared to the assurance provided by 100 percent identity testing, the identity of the dietary ingredient before use.

Section 111.75(a)(1) of the CGMP final rule reflects FDA’s determination that manufacturers that test or examine 100 percent of the incoming dietary ingredients for identity can be assured of the identity of the ingredient. However, FDA recognizes that it may be possible for a manufacturer to demonstrate, through various methods and processes in use over time for its particular operation, that a system of less than 100 percent identity testing would result in no material diminution of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing. To provide an opportunity for a manufacturer to make

such a showing and reduce the frequency of identity testing of components that are dietary ingredients from 100 percent to some lower frequency, FDA added to § 111.75(a)(1), an exemption from the requirement of 100 percent identity testing when a manufacturer petitions the agency for such an exemption to 100 percent identity testing under § 10.30 and the agency grants such exemption. Such a procedure would be consistent with FDA’s stated goal, as described in the CGMP final rule, of providing flexibility in the CGMP requirements. Section 111.75(a)(1)(ii) sets forth the information a manufacturer is required to submit in such a petition. The regulation also contains a requirement to ensure that the manufacturer keeps the FDA’s response to a petition submitted under § 111.75(a)(1)(ii) as a record under § 111.95. The collection of information in § 111.95 has been approved under OMB control number 0910–0606.

Description of Respondents: The respondents to this collection of information are firms in the dietary supplement industry, including dietary supplement manufacturers, packagers and re-packagers, holders, labelers and re-labelers, distributors, warehouses, exporters, importers, large businesses, and small businesses.

In the **Federal Register** of July 20, 2010 (75 FR 42095) FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
111.75(a)(1)(ii)	1	1	1	8	8

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

In the last 3 years, FDA has not received any new petitions to request an exemption from 100 percent identity testing of dietary ingredients; therefore, the agency estimates that one or fewer petitions will be submitted annually. Although FDA has not received any new petitions to request an exemption from 100 percent identity testing of dietary ingredients in the last 3 years, it believes that these information collection provisions should be extended to provide for the potential future need of a firm in the dietary supplement industry to petition for an

exemption from 100 percent identity testing of dietary ingredients. Based on our experience with petition processes, we estimate that the assembly of information in support of the petition required by § 111.75(a)(1)(ii) will take 8 hours.

Dated: September 27, 2010.
Leslie Kux,
Acting Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meeting

In accordance with section 10(d) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), announcement is made of a Health Care Policy and Research Special Emphasis Panel (SEP) meeting.

A Special Emphasis Panel is a group of experts in fields related to health care