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 No. 0910-0608

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

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 act) by adding section 402(g) of the act (21 U.S.C. 342(g)). Section 402(g)(2) of the 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 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 act (21 U.S.C. 371), FDA may issue regulations necessary for the efficient enforcement of the 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), pursuant to 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 No. 0910-0606.

We request OMB approval of the following information collection requirements:

21 CFR 111.75(a)(1)(ii) -- Reporting:
Sets forth the information a manufacturer is required to submit in a petition to request an exemption from 100 percent identity testing of dietary ingredients.

2. Purpose and Use of the Information Collection

The information will be used to show that a particular manufacturer of dietary supplements has successfully, or unsuccessfully, petitioned FDA for an exemption from 100 percent identity testing for ingredients used in supplement manufacture.

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. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

The regulation does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. Companies are free to use whatever forms of information technology may best assist them in preparing the petition and submitting it to the agency. 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 no petitions (0%) will be submitted electronically.

4. Efforts to Identify Duplication and Use of Similar Information

No duplication of Federal regulations concerning the process for petitioning for an exemption from 100 percent identity testing of dietary ingredients is likely because of the clear Congressional authorization that FDA promulgate regulations pertaining to the manufacture of dietary supplements as opposed to the jurisdiction of the U.S. Department of Agriculture (meats and poultry) and the Federal Trade Commission (advertising).

5. Impact on Small Businesses or Other Small Entities

FDA estimates that a substantial proportion (75%) of firms affected by this regulation are small businesses, and has kept their particular needs in mind throughout the development of these regulations. Small businesses with fewer than 20 employees were given an additional 2 years to comply with the 2007 final rule. Small businesses with 20 to 499 employees were given an

additional year to comply with the final rule. FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the administrative and scientific staffs within the Agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

A firm would submit a petition for an exemption from 100 percent identity testing of dietary ingredients occasionally, as needed. If the petition process being considered here was not conducted, the agency would have difficulty meeting its stated goal, as described in the CGMP final rule, of providing flexibility in the CGMP requirements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of July 20, 2010 (75 FR 42095). FDA received no comments.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

Information submitted to FDA in a petition for an exemption from 100 percent identity testing of dietary ingredients may contain trade secret and commercial confidential information. Confidential commercial information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), by section 301(j) of the act, and by part 20 of the agency's regulations (21 CFR part 20).

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

Table 1.-Estimated Annual Reporting Burden[1]

21 CFR Section	Number of Respondents	Annual Frequency per	Total Annual Responses	Hours per Response	Total Hours

		Response			
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.

12 b. Annualized Cost Burden Estimate

Gathering the information discussed here and providing it to the agency may be done by a professional employee. FDA estimates that the average hourly wage for this employee would be equivalent to a GS-11/Step-1 level in the locality pay area of Washington-Baltimore in 2010, approximately $29.93/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $59.86/hour. The overall estimated cost incurred by the respondents is $478.88 (8 burden hours x $59.86/hr = $478.88).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, or operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

At the agency, professional employees would review the petition. The review would require approximately forty hours. FDA estimates the hourly cost for review and evaluation of petitions to be $48.35 per hour, the GS-13/Step-5 rate for the Washington-Baltimore locality pay area for the year 2010. To account for overhead, this cost is increased by 100 percent, making the total cost $96.70 per hour. Thus, FDA estimates the cost to the Federal Government for the review of submissions to be $3,868 ($96.70/hour x 40 hours = $3,868).

15. Explanation for Program Changes or Adjustments

FDA estimates that the total annual burden has decreased from 3942 hours to 8 hours. This decrease was due to: (1) A program change of - 49 hours due to agency discretion i.e. the burden estimate was consolidated under the information collection, OMB No. 0910-0606 and (2) an adjustment of - 3,885 hours due to a decrease in the estimated number of respondents.

16. Plans for Tabulation and Publication and Project Time Schedule

The results of this information collection will not be published.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.