SUPPORTING STATEMENT

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

A. Justification

1. Need and Legal Basis

Section 402(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342 (g)) gives the Food and Drug Administration (FDA) explicit authority to issue a rule establishing Current Good Manufacturing Practice 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." Section 402(g)(2) of the act authorizes FDA to, by regulation, "prescribe good manufacturing practices for dietary supplements." Under section 701(a) of the act (21 U.S.C. 371), FDA may issue regulations necessary for the efficient enforcement of the act.

Given the above legal authority FDA has decided to redesignate § 111.75(a)(1) of the dietary supplement 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 codified provision set forth in this interim final rule 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 our 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, we recognize 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, we decided to add 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 our stated goal, as described in the CGMP final rule, of providing flexibility in the CGMP requirements.

We also include 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.

2. Information Users

Dietary supplement manufacturers, packagers and re-packagers, labelers, holders, and distributors will collect this information. 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.

This is a new collection of information.

3. Improved Information Technology

The facilities collecting the are free to use whatever method they wish, including automated, electronic, mechanical, other technological collection techniques, or other forms of information technology.

4. Duplication of Similar Information

The interim final rule does not represent a duplication of effort.

5. Small Businesses

The interim final rule will not have a significant economic impact on a substantial number of small businesses.

6. Less Frequent Collection

Less frequent collections of information would reduce the documentation that is intended to ensure that dietary supplements are manufactured, packaged, labeled, and held in a manner that will ensure the quality of the dietary supplement.

7. Special Circumstances

No special circumstances are associated with the collection of information.

8. Federal Register Notice/Outside Consultation

FDA is publishing this amendment as an interim final rule in order to provide an opportunity for interested persons to comment on whether this exemption procedure should be modified. This amendment procedure was developed as a result of comments on the dietary supplement CGMP proposed rule published on March 13, 2003 in the **Federal Register** Volume 68, No. 49, page 12158 and FDA public stakeholder meetings held on April 29, 2003 in College park, MD, on May 6, 2003 in Oakland, CA and on May 9, 2003 by satellite downlink with viewing sites at our district and regional offices throughout the country.

9. Payment/Gift to Respondent

No payment or gifts are associated with this collection of information.

10. Confidentiality

All information obtained by the agency will be reviewed in accordance with the guidelines set forth in the FDA Freedom of Information Regulations (21 CFR Part 20).

11. Sensitive Questions

This information collection does not contain questions of a sensitive nature (e.g., those regarding sexual behavior and attitudes, religious beliefs, etc).

12. Burden Estimate (Total Hours and Wages)

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.

The total estimated burden imposed by this collection of information is 11,826 hours to petition FDA and keep record of the Agency's response.

Table 1.--Estimated One-Time Burden to Petition FDA[1]

21 CFR Section	Number of Recordkeepers	Frequency per Recordkeeping	Total Records	Hours per Record	Total Hours
111.75 (a)1(b)	1,460	1	1,460	8	11,680
111.95	1,460	1	1460	0.1	146
				Total One time burden	11,826

[1]There are no capital costs or operating costs associated with the collection of information under this interim final rule.

In the regulatory impact analysis of the CGMP final rule, published elsewhere in this issue of the FEDERAL REGISTER, FDA identifies 1,460 establishments that manufacture, pack, hold, label, or otherwise process dietary supplements. We assume that at least some manufacturers would like to take advantage of the opportunity to petition the FDA to eliminate the need to do 100 percent identity testing for the dietary ingredients they use in the manufacture of their products. Therefore, we make an assumption that every establishment will submit a petition to the FDA for review and approval requesting an exemption from 100 percent identity testing for at least one dietary ingredient from at least one supplier. The petitions, which we assume would include the results of one year's testing, verification testing plan, and the supplier risk evaluation, will take 8 hours per plant for assembly of the information. Assuming that all establishments submit a petition for exemption for at least one dietary ingredient/supplier combination, the hour burden estimate for this activity is 11,680 hours (1,460 establishments x 8 hours per establishment).

We assume that the only recurring burden would be only for maintenance of records. The records of the verification testing would be subsumed under 21 CFR 111.325 of the final rule published elsewhere in this issue of the FEDERAL REGISTER. FDA's response to the petition submitted under § 111.75(a)(1)(ii) would be a new record associated with this IFR under 21 CFR 111.95. This would be, at a minimum, a one time burden for each establishment that petitioned the agency for an exemption. Again, assuming that each firm petitions the agency, the burden would be 146 hours (0.1 hours x 1460 firms).

13. Capital Costs (Maintenance of Capital Costs)

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

14. Cost to Federal Government

It will take FDA approximately 40 hours to review a petition. The cost of each petition review would be $1,826 ((40 hours x $45.65 per hour). If all 1,460 firms petition FDA one time, the total cost to government for these reviews would be $2,665,960.

15. Program or Burden Changes

This is a new collection; there are therefore no program changes or adjustments.

16. Publication or Burden Changes

The results of this information collection will not be published.

17. Display of OMB Approval Date

We are not seeking approval to not display the expiration date for OMB approval of the information collection.

18. Exceptions to the "Certification for Paperwork Act Submissions"

No exceptions to the certification statement were identified.