United States Food and Drug Administration

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 **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations. The Dietary Supplement Health and Education Act (Public Law 103–417) added section 402(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342(g)) which provides, in part, that the Secretary of Health and Human Services may, by regulation, prescribe good manufacturing practices for dietary supplements. Section 402(g) also 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 701(a) of the FD&C Act (21 U.S.C. 371(a)) gives FDA the authority to issue regulations necessary for the efficient enforcement of the FD&C Act. Accordingly, we have promulgated regulations at 21 CFR Part 111 establishing minimum current good manufacturing practice requirements for the manufacture, packaging, labeling, or holding of dietary supplements.

Subpart E of 21 CFR Part 111 (21 CFR 111.55-111.95) covers certain quality control specifications including component identity testing. Section 111.75(a)(1) provides for petitions to request an exemption from certain testing requirements under the regulation. According to § 111.75(a)(1)(ii), manufacturers may request an exemption when a dietary ingredient is obtained from one or more suppliers as 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.

Part 111.75(a)(1) 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 21 CFR 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.

Part 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 FDA's response to a petition submitted under § 111.75(a)(1)(ii) as a record under § 111.95.

We therefore request extension of OMB approval for the information collection provisions found in under 21 CFR 111.75 and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The information is used to show whether 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. Respondents to the information collection are individuals or firms who manufacture, package, label, or hold a dietary supplement. 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. Having received one petition over the past three years by electronic mail, we estimate 100% of respondents would utilize electronic means to satisfy the information collection.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. While OMB Control No. 0910-0606 (*Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements*) otherwise covers recordkeeping requirements under 21 CFR Part 111, this collection of information exclusively covers petitions covered under Subpart E. Upon our next renewal of OMB Control No. 0910-0606 we will consider whether it is appropriate to consolidate the collections.

5. Impact on Small Businesses or Other Small Entities

We estimate a substantial proportion (75%) of respondents are small businesses, however we do not believe the information collection imposes undue burden on small entities. At the same time, we assist small businesses in complying with our regulations through the availability of Regional Small Business Representatives and administrative and scientific staffs within the agency. We also provide a Small Business Guide on our website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Respondents to the collection may petition for an exemption from 100 percent identity testing of dietary ingredients occasionally as needed. Absent the petition process underlying the information collection, FDA would have difficulty meeting its public health safety objectives.

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), we published a 60 day notice for public comment in the Federal Register of April 9, 2018 (83 FR 15159). One comment was received suggesting that "*microbial cultures and probiotics should not be required to go through such a process to ensure exemption from the Agency's 100 percent identity testing requirement*," but did not suggest a revision to the estimated burden. We appreciate this comment, however, we believe that the current requirements impose minimal information collection while simultaneously ensuring the safety of dietary supplements.

Additionally, in December 2017, FDA received its first petition under the information collection, which is currently pending agency review. Because of overlap in processing the petition and publication submission deadlines, our 60-day and 30-day Federal Register notices communicated that we had not yet received a submission under the information collection. However, we believe we have accounted for the associated burden and therefore retain our current estimate. Should we receive additional petitions under the information collection, we will adjust our estimate accordingly prior to any future extension request.

9. Explanation of Any Payment or Gift to Respondents

No gifts or respondents are provided to respondents to the information collection.

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 FD&C 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

12a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

Table 1.-Estimated Annual Reporting Burden[1]

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
111.75(a)(1)(ii); Determining whether specifications are met	1	1	1	8	8

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

Since OMB's last review and approval of the information collection, we have received one petition. We therefore retain the currently approved estimated burden which assumes no more than one petition will be submitted annually. We further assume it takes respondents 8 hours to prepare the factual and legal information necessary to support a petition for exemption and to prepare the petition, for a total of 8 burden hours annually. These figures are based on our experience with the information collection.

12b. Annualized Cost Burden Estimate

Gathering the information discussed here and providing it to the agency may be done by a professional employee. Using 2018 OPM salary data, we assume an hourly wage commensurate to a GS-11/Step-1 Federal employee in the Washington/Baltimore locality of $32.60. Doubling this wage to account for overhead costs, we estimate an average hourly cost to respondents of $65.20/hour. The overall estimated cost incurred by respondents, therefore, is $521.60 (8 burden hours x $65.20/hr = $521.60).

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

Review of petitions under 21 CFR Part 111.75 is conducted by employees at least at the GS-13/5 level. Using OPM salary data we therefore assume an hourly cost for the review and evaluation of petitions of $52.66 per hour in the Washington-Baltimore locality for the year 2018. To account for overhead, we have increased this cost by 100%, for a total estimated cost to the Federal government of $4,212.80 ($105.32/hour x 40 hours = $4,212.80).

15. Explanation for Program Changes or Adjustments

We retain the currently approved burden estimate for the information collection. As noted previously under *Question 8* above, there was an overlap in processing a petition and publication

submission deadlines required for our 60-day and 30-day Federal Register notices. As a result, our notices communicated that we had not yet received a submission. While we have now received the first petition under the information collection, we believe we have accurately accounted for the associated burden.

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.