Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act

OMB Control No. 0910-0626

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(r)(6)) requires that a manufacturer of a dietary supplement making a nutritional deficiency, structure/function, or general well-being claim have substantiation that the claim is truthful and not misleading. Under section 403(r)(6)(A) of the FD&C Act, such a statement is one that "claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption for a nutrient or dietary ingredient."

The guidance document entitled, "Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act," provides our recommendations to manufacturers about the amount, type, and quality of evidence they should have to substantiate a claim under section 403(r)(6) of the FD&C Act. The guidance does not discuss the types of claims that can be made concerning the effect of a dietary supplement on the structure or function of the body, nor does it discuss criteria to determine when a statement about a dietary supplement is a disease claim. The guidance document is intended to assist manufacturers in their efforts to comply with section 403(r)(6) of the FD&C Act. The guidance document can be found at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm073200.htm#pra.

FDA is requesting OMB approval of the voluntary information collection provisions contained in the guidance document entitled, "Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act."

2. Purpose and Use of the Information Collection

Dietary supplement manufacturers collect the necessary substantiating information for their product as required by section 403(r)(6) of the FD&C Act. The guidance provides information to manufacturers to assist them in doing so. The recommendations contained in the guidance are voluntary. Dietary supplement manufacturers will only need to collect information to

substantiate their product's nutritional deficiency, structure/function, or general well-being claim if they choose to place a claim on their product's label.

Description of Respondents: The respondents to this collection of information are manufacturers of dietary supplements sold in the United States. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

The guidance 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 dietary supplement manufacturers. Companies are free to use whatever forms of information technology that may best assist them in voluntarily developing substantiation information as recommended in the guidance.

The agency estimates that one-hundred percent (100%) of the substantiating information will be maintained electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

This guidance will not result in a duplicative collection of information. The standard discussed in the guidance for substantiation of a claim on the labeling of a dietary supplement is consistent with standards set by the Federal Trade Commission (FTC) for dietary supplements and other health related products that the claim be based on competent and reliable scientific evidence. The FDA and FTC are the only Federal agencies that require respondents to develop substantiation information. Since both agencies use the same standard, if a firm has already collected data to satisfy FTC, then that information can be used or modified for this use. Therefore, there is no duplication.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that ninety percent (90 %) of respondents are small businesses. FDA recognizes that some dietary supplement manufacturers are small businesses, and has kept their particular needs in mind throughout the development of this guidance document. Dietary supplement manufacturers making a nutritional deficiency, structure/function, or general well-being claim are required by section 403(r)(6) of the FD&C Act to have substantiation that the claim is truthful and not misleading. There is no known way to reduce the burdens on a small business choosing to place a claim on their product's label. FDA notes, however, that the recommended information collection contained in the guidance is voluntary. FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative 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

Data collection occurs occasionally. There are no consequences to Federal program or policy activities if the information is not collected or is collected less frequently. Under section 403(r)(6) of the FD&C Act, a manufacturer of a dietary supplement cannot make a nutritional deficiency, structure/function, or general well-being claim on a dietary supplement product if it does not have substantiation that the claim is truthful and not misleading.

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 the Federal Register of November 4, 2014 (79 FR 65409), FDA published a 60-day notice requesting public comment on the proposed extension of this collection of information. Five comments were received. One comment agreed with the agency's burden estimate while the remaining comments were not responsive to the four information collection topics solicited in the notice and were therefore not addressed.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Information that is trade secret or confidential would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20).

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Description of Respondents: The respondents to this collection of information are manufacturers of dietary supplements sold in the United States. Respondents are from the private sector (for-profit businesses).

FDA estimates the burden for this information collection as follows:

Table 1. – Estimated Annual Recordkeeping Burden[1]					
Claim type	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in Hours)	Total Hours
Widely known, established	667	1	667	44	29,348
Pre-existing, not widely established	667	1	667	120	80,040
Novel	667	1	667	120	80,040
Total					189,428

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

Dietary supplement manufacturers will only need to collect information to substantiate their product's nutritional deficiency, structure/function, or general well-being claim if they chose to place a claim on their product's label. Gathering evidence on their product's claim is a one-time burden, in which they collect the necessary substantiating information for their product as required by section 403(r)(6) of the FD&C Act.

The standard discussed in the guidance for substantiation of a claim on the labeling of a dietary supplement is consistent with standards set by the Federal Trade Commission for dietary supplements and other health-related products that the claim be based on competent and reliable scientific evidence. This evidence standard is broad enough that some dietary supplement manufacturers may only need to collect peer-reviewed scientific journal articles to substantiate their claims; other dietary supplement manufacturers whose products have properties that are less well documented may have to conduct studies to build a body of evidence to support their claims. It is unlikely that a dietary supplement manufacturer will attempt to make a claim when the cost of obtaining the evidence to support the claim outweighs the benefits of having the claim on the product's label. It is likely that manufacturers will seek substantiation for their claims in the scientific literature.

The time it takes to assemble the necessary scientific information to support their claims depends on the product and the claimed benefits. If the product is one of several on the market making a particular claim for which there is adequate publicly available and widely established evidence supporting the claim, then the time to gather supporting data will be minimal; if the product is the first of its kind to make a particular claim or the evidence supporting the claim is less publicly available or not widely established, then gathering the appropriate scientific evidence to substantiate the claim will be more time consuming.

We assume that it will take 44 hours to assemble information needed to substantiate a claim on a particular dietary supplement when the claim is widely known and established. We believe it will take closer to 120 hours to assemble supporting scientific information when the claim is novel or when the claim is pre-existing but the scientific underpinnings of the claim are not widely established. These are claims that may be based on emerging science, where conducting

literature searches and understanding the literature takes time. It is also possible that references for claims made for some dietary ingredients or dietary supplements may primarily be found in foreign journals and in foreign languages or in the older, classical literature where it is not available on computerized literature databases or in the major scientific reference databases, such as the National Library of Medicine's literature database, all of which increases the time of obtaining substantiation.

In the Federal Register of January 6, 2000 (65 FR 1000), FDA published a final rule on statements made for dietary supplements concerning the effect of the product on the structure or function of the body. In that final rule, we estimated that there were 29,000 dietary supplement products marketed in the United States (65 FR 1000 at 1045). Assuming that the flow of new products is 10 percent per year, then 2,900 new dietary supplement products will come on the market each year. The structure/function final rule estimated that about 69 percent of dietary supplements have a claim on their labels, most probably a structure/function claim (65 FR 1000 at 1046). Therefore, we assume that supplement manufacturers will need time to assemble the evidence to substantiate each of the 2,001 claims (2,900 x 69 percent) made each year. If we assume that the 2,001 claims are equally likely to be pre-existing widely established claims, novel claims, or pre-existing claims that are not widely established, then we can expect 667 of each of these types of claims to be substantiated per year. Table 1 of this document shows that the annual burden hours associated with assembling evidence for claims is 189,428 (the sum of 667 x 44 hours, 667 x 120 hours, and 667 x 120 hours).

12b. Annualized Cost Burden Estimate

FDA estimates that the average hourly wage for the employee collecting information for substantiation would be equivalent to a GS-12/Step-1 level in the locality pay area of Washington-Baltimore in 2015, approximately $36.60/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $73.20/hour. Thus, the overall estimated cost incurred by the respondents is $13,866,129.60 (189,428 burden hours x $73.20/hour = $13,866,129.60). Several comment letters filed in response to the June 3, 2011 Federal Register notice noted that firms experience costs associated with hiring consultants to develop appropriate wording for claims, paying for full-text scientific literature and obtaining legal review of claims. The comments did not provide data supporting specific burden hours or hourly wage rates associated with consultants or legal reviewers. FDA deliberated over the comments it received in 2011 regarding its estimated costs for this collection, but made no adjustments in this submission. Under section 403(r)(6) of the FD&C Act, a manufacturer of a dietary supplement cannot make a nutritional deficiency, structure/function, or general well-being claim on a dietary supplement product *if it does not have substantiation that the claim is truthful and not misleading*. FDA believes commenters may have included in their cost estimate the time it takes to *research* and *generate* substantiation information for claims. The guidance provides our recommendations to manufacturers about the amount, type, and quality of evidence they should have to substantiate a claim under section 403(r)(6) of the FD&C Act. We believe that the substantiation information should have already been established by the respondent, as required under section 403(r)(6) of the FD&C Act, and thus the burden should reflect only the time necessary for *extract*ing and *summariz*ing that substantiation information. The guidance

does not discuss the types of claims that can be made concerning the effect of a dietary supplement on the structure or function of the body, nor does it discuss criteria to determine when a statement about a dietary supplement is a disease claim. Thus, we believe that costs associated with hiring consultants to develop appropriate wording for claims and obtaining legal review of claims are also not appropriate for inclusion in the cost estimate.

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

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

14. Annualized Cost to the Federal Government

FDA's review of the retained records would generally occur only as part of a regulatory action if FDA were to allege that a claim is unsubstantiated. FDA estimates that its review of the retained records would take 80 hours per action. FDA estimates the hourly cost for review and evaluation to be $ 60.49 per hour, the GS-15/Step-1 rate for the Washington-Baltimore locality pay area for the year 2015. To account for overhead, this cost is increased by 100 percent, making the total cost $120.98 per hour. Thus, FDA estimates the cost to the Federal Government for the review of records to be $9,678 per review ($120.98/hour x 80 hours). FDA estimates that it would review on average 2 records per year. Thus, FDA estimates that the total annual cost to the Federal Government would be $19,356 ($9,678 x 2 reviews).

15. Explanation for Program Changes or Adjustments

The hour burden is unchanged.

16. Plans for Tabulation and Publication and Project Time Schedule

The agency has no plans for publication of information from this information collection.

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.