

Supporting Statement
Food Labeling: Nutrition Labeling of Dietary Supplements on a “Per Day” Basis

A. Justification

1. Circumstances Necessitating Information Collection

Section 403(q)(5)(F) of the Federal Food, Drug, and Cosmetic Act (the act) (Attachment A) provides that dietary supplements must bear nutrition labeling in a manner that is appropriate for the product and that is specified in regulations issued by FDA. Section 101.36 (21 CFR 101.36) of FDA’s regulations (Attachment B) establishes the requirements for nutrition labeling of dietary supplements. FDA is amending its nutrition labeling regulations for dietary supplements to permit voluntary declaration of the quantitative amount and the percent of Daily Value of a dietary ingredient on a "per day" basis in addition to the required "per serving" basis, if a dietary supplement label recommends that the dietary supplement be consumed more than once per day. FDA published a proposed rule in the Federal Register of January 12, 1999 (64 FR 1765), to amend § 101.36, in response to a citizen petition requesting that we amend our dietary supplement nutrition labeling regulations to include this provision. The agency took this action to give manufacturers of dietary supplements the option to present nutrition information on a “per day” basis to consumers. The information collection provisions in § 101.36(e) were approved under OMB control number 0910-0395. When the final rule had not published in 2004, FDA requested that OMB discontinue the collection. Concurrently with the publication of the final rule, FDA is now requesting reinstatement of OMB approval under OMB control number 0910-0395 of the following information collection provisions contained in the amendments to § 101.36:

21 CFR 101.36(e) Third Party Disclosure

Section 101.36(e) would permit the voluntary declaration of the quantitative amount and the percent Daily Value of dietary ingredients on a "per day" basis in addition to the required "per serving" basis, if a recommendation is made on the label that the dietary supplement be consumed more than once per day.

2. How, by Whom, Purpose of Collection

FDA is requesting reinstatement of OMB approval under OMB control number 0910-0395 of the voluntary labeling provisions contained in § 101.36 (e). Consumers who purchase dietary supplements are the primary users of the information that may be disclosed on the label. Consumers may use the information to understand the total daily intake of each ingredient that they will receive from a product that is recommended for consumption multiple times per day.

3. Consideration Given to Information Technology

Section 101.36(e) 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 voluntarily revising their dietary supplement labels to include “per day” information.

4. Identification of Duplicative Information

No duplication of Federal regulations concerning the declaration of the quantitative amount by weight and the percent Daily Value for dietary ingredients is likely because of the clear Congressional authorization that FDA issue regulations pertaining to dietary supplements as opposed to the jurisdiction of the U.S. Department of Agriculture (meats and poultry) and the Federal Trade Commission (advertising). There should be no duplicative information collection as a result of this final rule.

5. Small Businesses

The changes allowed to dietary supplement labeling by this final rule are voluntary, no firm is required by regulation to change their labels to include “per day” information. Only firms that will benefit from including “per day” information on their food labels will choose to do so.

6. Less Frequent Information Collection

There are no consequences to Federal program or policy activities if the information is not collected or is collected less frequently. This information is voluntary on the part of the dietary supplement producer.

7. Special Circumstances

Allowing manufacturers of dietary supplements to put “per day” information on their food labels does not involve submission of information to the agency, written responses to the agency, retention of records for more than three years, the use of statistical methods, pledges of confidentiality by FDA, or require the disclosure of trade secrets or other confidential information.

8. Consultations with Persons Outside FDA

In the Federal Register of January 12, 1999 (64 FR 1765), FDA published a proposed rule asking for comments on the voluntary labeling provisions of § 101.36(e). No comments were received on the information collection.

9. Payment or Gift

This information collection does not provide for payment or gifts to respondents.

10. **Confidentiality**

There are no confidentiality issues associated with this information collection.

11. **Privacy Sensitive Questions**

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

12. **Burden of Information Collection**

FDA estimates the burden of the collection of information described in the above programs as follows:

Description of Respondents: Suppliers of dietary supplements.

Table 1. -- Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Annual Hours	Total Operating Costs
101.36(e)	125	13	1625	0.25	406	\$151,000

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

These estimates are based on agency communications with industry (64 FR 1765 at 1768) and our knowledge of, and experience with, food labeling. The agency estimated in the March 13, 2003, proposed rule entitled “Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements (68 FR 12157 at 12223) that there were about 1250 manufacturers and relabelers of dietary supplements. Based on data in our labeling cost model each producer has, on average, roughly 50 products. We assume that only 10 percent, or 125, of the dietary supplement suppliers would revise the labels of their products to incorporate “per day” information for their products. We also assume that “per day” information would generally be placed on at most 25 percent, or at most 13, of a firm's estimated 50 products, although this number would vary by firm based on the types of products that it produces. The agency also believes that the burden associated with providing nutrition information on a “per day” basis for dietary supplements would be a one-time burden for the small number of firms that decide voluntarily to add this additional information to the labels of their products, separate from any other label changes for their products.

Cost to Respondents

We estimate that at least 90 percent of firms would coordinate adding “per day” information with other changes to their labels. In this case, the voluntary cost of transmitting “per day” information to consumers would be subsumed almost entirely in the cost of these other voluntary or required labeling changes. The incremental cost for these 113 firms would be approximately \$50 per label for 1469 labels, or about \$73,000 total (64 FR 1765 at 1768). For the remaining 12 firms that would not coordinate adding “per day” information with other labeling changes, we estimate that the cost would be approximately \$500 per label for 156 labels, or \$78,000 total (64 FR 1765 at 1768-69). The estimated total operating costs in Table 1 of this document are, therefore, \$151,000. There are no capital costs or maintenance costs associated with this collection of information.

13. Estimate of Other Costs to Respondents.

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

14. Cost to the Federal Government

There are no annualized costs to the Federal Government as a result of this rule.

15. Reason for Change

The total annual burden has increased from 276 hours to 406 hours. This increase is due to an increase in the number of producers of dietary supplements.

16. Statistical Reporting

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

17. Display of OMB Approval Date

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”

No exceptions to the certification statement identified in Item 19 of the instructions for completing OMB Form 83-I have been identified.