

SUPPORTING STATEMENT

FOOD LABELING: NUTRITION LABELING OF DIETARY SUPPLEMENTS ON A "PER DAY" BASIS

A. JUSTIFICATION

1. Necessity of the Information Collection

Section 403(q) (21 U.S.C. 343(q)) of the Federal Food, Drug, and Cosmetic Act (the act), which was added by the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), established the requirements for nutrition labeling of food. In particular, section 403(q) of the act specifies the nutrition information and other information that must be present on the label or label of food products. With respect to dietary supplements, section 403(q)(5)(F) of the act, as amended by the Dietary Supplement Health and Education Act of 1994 (the DSHEA), among other things, provides that a dietary supplement shall comply with the requirements for nutrition labeling in a manner specified in regulations issued by the Food and Drug Administration, including the listing of the quantity of each dietary ingredient per serving.

In a final rule entitled "Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements; Compliance Policy Guide, Revocation" (hereinafter referred to as "the September 1997 final rule") that published in the Federal Register of September 23, 1997 (62 FR 49826), FDA established requirements for statement of identity, nutrition labeling, and ingredient labeling of dietary supplements in response to the provisions of section 403(q)(5)(F) of the act. Section 101.36(b)(2) (21 CFR 101.36(b)(2)) which becomes effective on March 23, 1999) provides that the quantitative amount and the percent of daily value of dietary ingredients shall be declared on a "per serving" basis and may be voluntarily declared on a "per unit" basis.

In response to a citizen petition, FDA is proposing to amend § 101.36 to provide that the quantitative amounts and the percent of Daily Value of dietary ingredients may be voluntarily presented on a "per day" basis, if a recommendation is made on the label that the dietary supplement be consumed more than once per day. FDA is advising that it does not intend to object to manufacturers declaring information on a per day basis prior to issuance of a final rule, provided it is presented in a manner consistent with the proposal. FDA notes that manufacturers should be aware that a final rule on this issue may differ from this proposal and that they would be required to change their labels to conform to the final rule.

FDA is requesting OMB approval of the following information collection provisions contained in the proposed amendments to § 101.36:

21 CFR 101.36(e)(9)

Third Party Disclosure

Would permit producers of dietary supplements to provide voluntarily 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, and for What Purpose Information is Used

The user of the information on the "per day" quantitative amounts and percent Daily Values for dietary ingredients would be the consumer that purchases the dietary supplement. This information may be useful to impress upon consumers of dietary supplement products the total daily intake of each ingredient that they will receive from a product that is recommended for consumption multiple times per day.

3. Use of Improved Information Technology

This proposed 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 revising their labeling.

4. Identification of Duplication and Similar Information Already Available

No duplication of Federal regulations concerning the proposed regulation to permit 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 promulgate 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).

5. Small Business

The proposed provisions are no more burdensome for small businesses than for large. The proposed provisions are voluntary

and would presumably only be used if to the advantage of the firm.

6. Consequences if Data Were Collected Less Frequently

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. Alternative information is required by existing regulations.

7. Special Circumstances

Not applicable.

8. Outside Consultation

The agency consulted with the petitioner and two producers of dietary supplements concerning the potential impact of the proposed rule. Publication of this proposal will provide an opportunity for persons outside the agency to offer their comments on the proposed amendment to permit the quantitative amount and the percent Daily Value of a dietary ingredient to be voluntarily presented on a "per day" basis, if a recommendation is made on the label that the dietary supplement be consumed more than once per day.

9. Gifts

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

10. Confidentiality

Information that is trade secret or confidential is subject to FDA's regulations on the release of information, 21 CFR Part 20.

11. Sensitive Questions

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

12. Respondent Hour Burden and Annualized Burden Hour Costs Estimates

Burden Hours

FDA estimates the total annual hour burden for this proposed

collection to be 213 hours as follows:

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) | 85 | 10 | 850 | 0.25 | 213 | \$83,000 |

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

These estimates are based on agency communications with industry and FDA's knowledge of and experience with food labeling. FDA has previously estimated that there were a maximum of 850 suppliers of dietary supplements and that each supplier had 40 products whose labels required revision. FDA expects that only 10 percent, or 85, of the dietary supplement producers would revise the labels of their products to incorporate nutrition levels for the daily use of its products. FDA also expects that daily use levels for nutrition information would generally be placed on at most 25%, or at most 10, of a firm's estimated 40 products, although this number would vary by firm based on the types of products that it produces. FDA also believes that the burden associated with the disclosure of nutrition information on a daily use basis for dietary supplements that would be required by this proposed rule will be a one-time burden for the small number of firms that decide voluntarily to add this additional information to the labels for their products. Respondents are already required to disclose the quantitative amount and daily value of dietary ingredients per serving as part of the nutrition information for dietary supplements. Respondents may also provide such information on a per unit basis. The information required under the proposed rule would be generated by simple extrapolation from that information.

Estimated Annualized Cost for the Burden Hours

FDA estimates that the annualized cost to the respondents for the hour burden associated with the information collection provisions of this proposed regulations would be approximately \$1065. This estimate presumes that the hourly cost to a firm voluntarily providing "per day" information would not exceed the base hourly rate of a GS-13 salary (\$25) plus overhead expenses estimated as being equal to salary, or \$50.

13. Annual Cost Burden to Respondent

FDA estimates that at least 90 percent of firms would coordinate addition of "per day" use nutrition information with other changes in their labels, in which case the voluntary cost of transmitting the information to consumers in labeling would be

subsumed almost entirely in the cost of these other voluntary or required labeling changes. The incremental cost for these 76 firms would be approximately \$50 per label for 760 labels, or \$38,000 total. For the remaining 9 firms that would not coordinate changes with other labeling changes, FDA estimates that the cost would be approximately \$500 per label for 90 labels, or \$45,000 total. The estimated total operating costs in Table 1 are, therefore, \$83,000. There are no capital costs or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

FDA estimates that the annualized cost to the Federal Government will be minimal. Any costs due to this proposed labeling change will be absorbed by the agency as part of the overall cost of its programs for ensuring compliance with the requirements for nutrition labeling.

15. Changes of Adjustments in Burden

The increase in the hour burden is due to the proposed establishment of a new recordkeeping requirement.

16. Statistical Analysis, Publication Plans, and Schedule

Not Applicable

17. Approval Not to Display Expiration Date

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

18. Exceptions to the Certification Statement Identified in Item 19

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

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

There are no plans to publish the information collected under the provisions of this proposed regulation for statistical use. The collection of information required under the provisions of this proposed regulation do not employ statistical methods.