

**SUPPORTING STATEMENT**  
**Record Retention Requirements**  
**for the Soy Protein/CHD Health Claim**  
**0910-0428**

**A. JUSTIFICATION**

**1. Necessity of the Information Collection**

Section 403(r)(3)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(3)(A)(i)) provides for the use of food label statements characterizing a relationship of any nutrient of the type required to be in the label or labeling of the food to a disease or a health related condition only where that statement meets the requirements of regulations authorizing the use of such a health claim (Appendix A). The Food and Drug Administration (FDA) has published regulations defining the circumstances under which claims may be made about nutrients in foods. Section 101.82 (21 CFR 101.82) of FDA's regulations authorizes a health claim for food labels about soy protein and the risk of coronary heart disease (Appendix B). To bear the soy protein/coronary heart disease health claim, foods must contain at least 6.25 grams of soy protein per reference amount customarily consumed. Analytical methods for measuring total protein can be used to quantify the amount of soy protein in foods that contain soy as the sole source of protein. However, at the present time there is no validated analytical methodology available to quantify the amount of soy protein in foods that contain other sources of protein. For these latter foods, FDA must rely on information known only to the manufacturer to assess compliance with the requirement that the food contain the qualifying amount of soy protein. Thus, FDA requires manufacturers to have and keep records to substantiate the amount of soy protein in a food that bears the health claim and contains sources of protein other than soy, and to make such records available for review and copying by appropriate regulatory officials upon request and during site visits. The information collected includes nutrient data bases or analyses, recipes or formulations, purchase orders for ingredients, or any other information that reasonably substantiates the ratio of soy protein to total protein.

We request OMB approval for extension of the following information collection requirements contained in § 101.82:

**21 CFR 101.82 Record Retention and Review**

Requires food manufacturers to retain, and make available to regulatory officials, records concerning the ratio of soy protein to other sources of protein in a food product bearing a soy protein/CHD health claim.

**2. How, by Whom, and for What Purpose Information is Used**

The information is used by FDA during inspection review of firms' label claims to determine the basis of soy protein/CHD health claims. The purpose of the information collection is to permit calculation of the ratio of soy protein to other sources of protein in a food when that food bears a soy protein/CHD health claim. The agency believes that requiring records retention

in this circumstance for soy protein/CHD health claims is necessary for the efficient enforcement of the act. Without access to this information, FDA is unable to ensure that food products that contain non-soy proteins comply with the requirements for the soy protein/CHD health claim.

### **3. Use of Improved Information Technology**

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 retaining the appropriate records and making them available to regulatory officials.

### **4. Identification of Duplication and Similar Information Already Available**

No duplication of Federal regulations concerning the regulation for a health claim for soy protein is likely because of the clear Congressional authorization that FDA promulgate regulations pertaining to health claims for foods 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 notification procedures are no more burdensome for small businesses than for large. The requirements are the minimum requirements for the health claim for soy protein and CHD.

### **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. Under the regulations, a food manufacturer could not use a soy protein/CHD health claim on a food product containing non-soy sources of protein if it did not retain the appropriate records for possible review by regulatory officials.

### **7. Special Circumstances**

Not applicable.

### **8. Outside Consultation**

In accordance with 5 CFR 1320.8(d), on August 23, 2005, FDA published a 60-day notice for public comment (Appendix C) in the Federal Register (70 FR 49295). One comment was received that was not related to the information collection.

### **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 hour burden for this information collection to be 25 hours, as follows:

**ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>**

21 CFR Section	No. Of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
101.82(c)(2)(ii)(B)	25	1	25	1	25

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based upon its experience with the use of health claims, FDA estimates that only about 25 firms would be likely to market products bearing a soy protein/CHD health claim and that only, perhaps, one of each firm’s products might contain non-soy sources of protein along with soy protein. The records required to be retained by § 101.82(c)(2)(ii)(B) are the records, e.g., the formulation or recipe, that a manufacturer has and maintains as a normal course of its doing business. Thus, the burden to the food manufacturer is that involved in assembling and providing the records to appropriate regulatory officials for review or copying.

Estimated Annualized Cost for the Burden Hours

FDA estimates that the cost for the retention and disclosure of records for food products under this regulation would equal approximately \$1,800. In this calculation of cost, FDA estimates that the average hourly cost for retaining the records and making them available to regulatory officials would be equivalent to that of a GS-13 base salary of \$36. Twenty-five total annual burden hours multiplied by \$36/hour equals \$900. To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondents \$1,800.

**13. Annual Cost Burden to Respondent**

FDA believes that the requirements do not result in a cost burden, other than the hour burden, to respondents. The information that a firm is required to retain and make available is the information that the firm would use as a basis for a soy protein/CHD health claim on its products. Thus, these are costs that would be incurred by a firm as a normal cost of doing business and are, therefore, not associated with this collection.

**14. Annualized Cost to the Federal Government**

FDA’s review of the retained records would generally occur as part of its scheduled inspection of a food firm. FDA has estimated the annualized cost to the Federal Government for the review of records retained by firms as support for soy protein/CHD claims under §101.82(c)(2)(ii)(B), based on the estimated number of products for which records are retained, as follows:

Estimated number of hours per year	= 25 x 1	= 25 hours; or
Estimated number of products	= 25	
Estimated number of hours for the review and evaluation of the records	= 25	
Estimated cost for review and evaluation	= \$1,800	
Total time of 25 hours x \$36/hour for review and evaluation (salary)	= \$900	
Overhead	= \$900	

Total cost (Salary + Overhead) = \$1,800

Hourly cost for review and evaluation of the cost to the Federal government is estimated as being equivalent to that of a base GS-13 salary. To account for overhead, this cost is increased by 100 percent.

**15. Changes of Adjustments in Burden**

Not Applicable

**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 regulation for statistical use. The collection of information that is required under the provisions of this regulation does not employ statistical methods.