RECORD RETENTION REQUIREMENTS
FOR THE SOY PROTEIN/CHD HEALTH CLAIM

OMB No. 0910-0428

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 403(r)(3)(A)(i) of the Federal Food, Drug, and Cosmetic 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 the regulations promulgated by the Secretary to authorize the use of such a health claim. 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. 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 to appropriate regulatory officials upon written request. 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 -- Recordkeeping
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. Purpose and Use of the Information Collection

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

4. Efforts to Identify Duplication and Use of Similar Information

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. Impact on Small Businesses or Other Small Entities

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 of Collecting the Information 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 Relating to the Guidelines of 5 CFR 1320.5

None of the requirements are inconsistent with the guidelines in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of October 23, 2008 (73 FR 63157). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

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

10. Assurance of Confidentiality Provided to Respondents

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

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden[1]					
21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
101.82(c)(2)(ii)(B)	25	1	25	1	25

[1] 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/coronary heart disease health claim and that only, perhaps, one of each firm's products might contain nonsoy 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 the annualized burden hour cost to a respondent for retention and disclosure of the required records to be approximately $1,988. FDA estimates a respondent's average wage to be that of a Federal government employee at the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2008, which makes the annual wage cost for retention and disclosure approximately $993.75 (25 hours x $39.75 per hour). To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondents $1,987.50, rounded to $1,988.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

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

14. Annualized Cost to Federal Government

FDA's review of the retained records would generally occur as part of its scheduled inspection of a food firm. FDA estimates that its review of the retained records would take one hour per product (25 products x one hour = 25 hours). Thus, FDA estimates the annual cost to the Federal Government to be 25 hours at rate of $39.75/hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2008 (25 hours x $39.75 /hour = $993.75). To account for overhead, this cost is increased by 100 percent, making the total estimated annual cost to the Federal Government $1,987.50, rounded to $1,988.

15. Explanation for Program Changes or Adjustments

There is no change in the burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

The information obtained from 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.