

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.

In the **Federal Register** of August 23, 2005 (70 FR 49295), FDA published a 60-day notice requesting public comment on the information collection provisions. One comment was received that was not related to the information collection.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR section	Number 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

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.

Dated: November 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–22636 Filed 11–14–05; 8:45 am]

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FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0574. The approval expires on April 30, 2006. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: November 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DATES: All letters of interest and nominations should be received on or before December 15, 2005.

ADDRESSES: Letters of intent and nominations for membership should be submitted to Jayne Peterson (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT:

Jayne Peterson, Advisors and Consultants Staff (HFD–21), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, e-mail: petersonj@cder.fda.gov.

SUPPLEMENTARY INFORMATION: The agency requests nominations for a nonvoting industry representative to serve on the Nonprescription Drugs Advisory Committee.

I. Function

The function of the committee is to review and evaluate available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this notice. Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0424]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Survey on Program Funding

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Survey on Program Funding” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Nonvoting Member Representing Industry Interests on a Public Advisory Committee; Nonprescription Drugs Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for a nonvoting industry representative to serve on the Nonprescription Drugs Advisory Committee.