

evaluation of the effectiveness of ORR employability services through RSS and TAG, and (2) propose options for institutionalizing ongoing evaluation and performance assessment into the programs. ORR is requesting OMB clearance for three methods of information collection: (1) Interviews with state and local refugee program administrators and service providers in three sites to learn about service delivery and organizational arrangements, and with a small number of local employers who work with RSS- and TAG-funded service providers to learn about their experiences with the programs; (2) a sample of 1,125 refugees

to collect data on refugees' employment and earnings outcomes; (3) two to four focus groups with seven to ten program clients in each of the three sites to obtain customer perspectives of the services they received and their adjustment experiences.

#### Respondents

(1) Interviews will be conducted with three state refugee coordinators, voluntary agency (VOLAG) and Mutual Assistance Association (MAA) staff, local RSS and TAG service providers, and employers who employ significant numbers of refugees.

(2) The respondents of the survey are refugees who have been in the United

States for fewer than five years, and, thus, are eligible for RSS and TAG services. The survey relies on a mixed-mode data collection method that involves both telephone and in-person interviews. If individuals cannot be reached by phone, an attempt will be made to contact them in person.

Approximately 900 of the 1,125 refugees sampled will complete the survey over a nine-week period.

(3) Respondents of the focus groups will include refugees who have received RSS- and TAG-funded services. Approximately 70 refugees will participate in the focus groups.

#### ANNUAL BURDEN ESTIMATES

| Instrument                             | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|--|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Interviews with program staff .....    | 60                    | 1                                  | 1                                 | 60                 |
| Interviews with employers .....        | 12                    | 1                                  | 2                                 | 24                 |
| Survey of refugees .....               | 900                   | 1                                  | 0.75                              | 675                |
| Focus group with program clients ..... | 70                    | 1                                  | 2                                 | 140                |

Estimated Total Annual Burden Hours: 899.

#### Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

#### OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: [Katherine\\_T\\_Astrich@omb.eop.gov](mailto:Katherine_T_Astrich@omb.eop.gov).

Dated: November 8, 2005.

**Robert Sargis,**

*Reports Clearance Officer.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. 2005N-0317]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. **DATES:** Fax written comments on the collection of information by December 15, 2005.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

#### FOR FURTHER INFORMATION CONTACT:

Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim—21 CFR 101.82(c)(2)(ii)(B) (OMB Control Number 0910-0428)—Extension

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 issued by the Secretary of Health and Human Services 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.

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 BURDEN<sup>1</sup>

| 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          |

<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/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.*

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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](mailto: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.