DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Preliminary Investigation of Health Effects of Occupational Exposures in Paducah Gaseous Diffusion Plant (PGDP) Workers

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Preliminary Investigation of Health Effects of Occupational Exposures in Paducah Gaseous Diffusion Plant (PGDP) Workers.

Times and Dates:

8 a.m.–8:30 a.m., December 18, 2001 (Open)

8:40 a.m.-12:30 p.m., December 18, 2001 (Closed).

Place: Embassy Suites Hotel, 1900 Diagonal Road, Alexandria, Virginia 22314.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Deputy Director for Program Management, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of application received under the Memorandum of Understanding between the Department of Energy and the Department of Health and Human Services.

Contact Person for More Information: Kathleen Goedel, National Institute for Occupational Safety and Health, CDC, 4676 Columbia Parkway, M/S R–6, Cincinnati, Ohio 45226, telephone 513–841–4560.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 23, 2001.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–29732 Filed 11–29–01; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0249]

Agency Information Collection Activities; Announcement of OMB Approval; Consumer and Producer Surveys on Economic Issues

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Consumer and Producer Surveys on Economic Issues'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 31, 2001 (66 FR 46018), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. 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 0910–0478. The approval expires on May 31, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: November 21, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–29743 Filed 11–29–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0319]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Health and Diet Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by December 31, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (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.

Health and Diet Survey

The authority for FDA to collect the information derives from the authority of the Commissioner of Food and Drugs, as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)). The Health and Diet Survey will provide FDA information about consumers' knowledge, perceptions, attitudes, and practices related to dietary supplements and food. A nationally representative sample of 2,000 adults in the 48 contiguous States and the District of Columbia will be selected at random and interviewed by telephone. Participation will be voluntary. The survey will collect information about: (1) Prevalence, experience, and purposes of use of dietary supplements; (2) knowledge of health benefits, health risks, and regulation of dietary supplements; (3) sources of dietary

supplement information; (4) perceptions of dietary supplement labels; (5) replacement and combination use of supplements and drugs; (6) adverse experience with dietary supplements; (7) children's and teenagers' use of dietary supplements; (8) knowledge of diet-health relationships; (9) dietary management practices; and (10) use of food labels.

Some of the questions to be asked (items 8 through 10 listed in the previous paragraph) replicate the ones asked in the 1995 Health and Diet Survey. Responses to these questions will help FDA identify and measure any changes in consumer knowledge, perceptions, attitudes, and practices with regard to diet, health, and use of food labels. The information will also help the agency evaluate the effectiveness of the Nutrition Labeling and Education Act of 1990 in promoting the public health.

The agency will use the other questions in the proposed survey to enhance its understanding of consumer knowledge, perceptions, attitudes, and practices regarding dietary supplements. Subsequent to the enactment of the Dietary Supplement Health and Education Act of 1994 (DSHEA), the consumption of dietary supplements in the United States has been increasing. FDA needs current, timely, and policy-relevant consumer information to help it identify needs for and develop consumer education programs and regulatory policies to ensure safe and appropriately labeled supplement products. The survey will help the agency measure prevalence and distribution of consumer knowledge, perceptions, attitudes, and practices. This information can be used to understand and describe the consumer environment that is the intended target of labeling and education initiatives.

In the **Federal Register** of August 7, 2001 (66 FR 41245), the agency requested comments on the proposed collection of information.

FDA received 11 comments in response to the **Federal Register** announcement. Comments generally supported the need of the proposed information collection for the proper performance of FDA's functions. None of the comments were on the estimated burden or ways to minimize the burden of the planned information collection. Issues mentioned in the eight comments received from eight private citizens are beyond the scope of the proposed information collection; these issues will not be discussed here.

One comment urged FDA to include questions regarding consumers' use of and attitudes toward fortified foods. The comment states that the information on fortified foods will help FDA assess the need to revise and update its food fortification policy guidelines and will provide initial direction for the process. Examples of proposed topics of inquiry include: (1) Profile of fortified food users and their patterns of use; (2) consumer knowledge of the upper limits of intake of vitamins and minerals; (3) fortified food consumers' attention to the amounts of particular vitamin or mineral consumed from fortified foods, dietary supplements, and natural food sources; (4) consumer belief of nutritional adequacy from one or two heavily fortified foods; (5) levels of calcium consumption from calcium fortified foods; and (6) whether consumers of calcium-fortified foods consider these foods an adequate substitute for consuming foods naturally rich in calcium such as dairy foods.

FDA notes that, although it has an inherent interest in reviewing and evaluating its current fortification policy, it has more immediate needs of current, timely, national, and policy-relevant consumer information on dietary supplements to carry out its statutory functions. FDA also notes that any inclusion of questions on fortified foods in the proposed instrument would require introduction and explanation of this novice product category that, despite the popularity of certain products, has not been widely recognized by consumers. The introduction and explanation would be needed to provide an appropriate context so participants could shift their attention from dietary-supplement topics to fortified-food topics and could understand the kinds of products under discussion. FDA does not believe the proposed instrument is capable of obtaining valid and useful information on both dietary supplements and fortified foods without significantly increasing participant burden. Thus, the agency has chosen to maintain the focus of the information collection on dietary supplements only.

One comment stated that the proposed information collection is not necessary for the proper enforcement of FDA's statutory obligations because: (1) The information described in the **Federal Register** announcement is already available, and (2) FDA should focus on enforcement of the current regulations that govern dietary supplement products and on completion of those regulations that are still necessary for finalization of the implementation of the DSHEA.

FDA has conducted a thorough literature review to identify extant, accessible, and similar information that could serve the agency's purpose. The agency has concluded that the existing information cannot be used for the purpose of the proposed information collection because: (1) Available consumer surveys have three major limitations that inhibit their use as a substitute for this collection of information: out-of-date information, limited focuses, and regional coverage; and (2) available focus group studies provide qualitative rather than quantitative information.

FDA recognizes its enforcement role in implementing the DSHEA. Part of that role includes establishing regulations and guidelines, where appropriate, to ensure that the dietary supplements currently used by consumers meet the requirements of the DSHEA. The agency is making progress in completing those regulations that are still necessary for finalization of the implementation of the DSHEA. Meanwhile, in order to carry out its enforcement functions efficiently, the agency also needs current, timely, and policy-relevant consumer information that can aid the agency in evaluating its labeling policies and in identifying potentially unsafe products. The proposed collection of information can provide such information. The agency, however, is not aware of the availability of any other source of information that can be used for this purpose.

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

TABLE1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Cognitive interview	9	1	9	1.5	13.5
Pretest	9	1	9	0.5	4.5
Screener	4,200	1	4,200	0.02	84

TABLE1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Survey	2,000	1	2,000	0.5	1,000
Total					1,102

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on FDA's experience with previous consumer surveys. Prior to the administration of the survey, the agency plans to conduct a series of nine cognitive interviews and a series of nine pretests to ensure the quality of the survey. Cognitive interviews will help the agency understand respondent comprehension of the meanings of questions and words, and how respondents answer questions. Pretests will help the agency examine and reduce problems in the administration of the final questionnaire. The agency will use a screener to select an eligible respondent in each household to participate in the survey.

Dated: November 21, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–29742 Filed 11–29–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 01D–0294 and 01D–0295]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Providing Regulatory Submissions in Electronic Format for Food Additive and Color Additive Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by December 31, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (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.

Providing Regulatory Submissions in Electronic Format for Food Additive and Color Additive Petitions

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe unless: (1) It and its use or intended use are in conformity with a regulation prescribing the condition(s) under which such additive may safely be used; (2) it and its use or intended use conform to the terms of a regulatory exemption for investigational use; or (3) for a food contact substance, the substance and the use of such substance are in conformity with a regulation prescribing the conditions under which such additive may be safely used or a food contact notification submitted under section 409(h) of the act is effective. Individuals or companies submit food additive petitions to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. The regulation in 21 CFR 171.1 specifies the information that a petitioner must submit in order to establish that the proposed use of a food additive is safe for its proposed use. This regulation implements section 409(b)(2) of the act.

Section 721(a) of the act (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless: (1) The additive and its use are in conformity with a regulation listing such additive for such use, including any provision that describes the condition(s) under which the additive may safely be used and is either batch certified for such use or exempted from the certification requirements; or (2) the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of the act. Individuals or companies submit color additive petitions to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is already approved. The regulation in 21 CFR 71.1 specifies the information that a petitioner must submit in order to establish that a color additive is safe and suitable for its proposed use.

Respondents to this collection of information are businesses engaged in the manufacture or sale of food, food ingredients, substances used in materials that come into contact with food or engaged in the manufacture or sale of foods, drugs, devices, or cosmetics containing color additives.

The agency estimates that up to 30 percent of the petitioners for both food and color additives will take advantage of the electronic submission process during the first year. By using the guidelines, including the forms that FDA is providing, the petitioner will be able to organize the petition to focus on the information needed to expedite review of the petition. Therefore, we estimate that petitioners will only need to spend approximately 1 hour completing the electronic submission application form (FDA Form 3503 or 3504, as appropriate) because they will have already organized the information needed for the submission into the appropriate categories.

In the **Federal Register** of July 31, 2001 (66 FR 39517), the agency requested comments on the proposed collection of information. No comments were received.

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