

240,000; *Total Annual Responses*: 240,000; *Total Annual Hours*: 80,000. (For policy questions regarding this collection contact Claudette Sikora at 410-786-5618. For all other issues call 410-786-1326.)

3. *Type of Information Collection*

Request: Reinstatement without change of a previously approved collection.

Title of Information Collection: Monthly State File of Medicaid/Medicare Dual Eligible Enrollees. *Use*: The monthly data file is provided to CMS by states on dually eligible Medicaid and Medicare beneficiaries, listing the individuals on the Medicaid eligibility file, their Medicare status and other information needed to establish subsidy level, such as income and institutional status. The file will be used to count the exact number of individuals who should be included in the phased-down state contribution calculation that month. CMS will be able to merge the data with other data files and establish Part D enrollment for those individuals on the file. The file may be used by CMS partners to obtain accurate counts of duals on a current basis. *Form Number*: CMS-10143 (OCN 0938-0958).

Frequency: Monthly. *Affected Public*: State, Local, or Tribal Governments.

Number of Respondents: 51. *Total Annual Responses*: 612. *Total Annual Hours*: 6,120. (For policy questions regarding this collection contact Goldy Austen at 410-786-6450. For all other issues call 410-786-1326.)

4. *Type of Information Collection*

Request: Reinstatement without change of a previously approved collection.

Title of Information Collection: Medicare Credit Balance Reporting Requirements and Supporting Regulations in 42 CFR 405.371, 405.378 and 413.20; *Use*: Section 1815(a) of the Act authorizes the Secretary to request information from providers which is necessary to properly administer the Medicare program. Quarterly credit balance reporting is needed to monitor and control the identification and timely collection of improper payments. The information obtained from Medicare credit balance reports will be used by the contractors to identify and recover outstanding Medicare credit balances and by federal enforcement agencies to protect federal funds. The information will also be used to identify the causes of credit balances and to take corrective action. *Form Number*: CMS-838 (OCN: 0938-0600); *Frequency*: Yearly; *Affected Public*: Private sector—Business or other for-profits; *Number of Respondents*: 45,838; *Total Annual Responses*: 183,352; *Total Annual Hours*: 550,056. (For policy questions regarding this collection contact Milton

Jacobson at 410-786-7553. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *November 16, 2012*:

1. *Electronically*. You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail*. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: September 11, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Administration on Intellectual and Developmental Disabilities (AIDD); Notice of Meeting

AGENCY: President's Committee for People with Intellectual Disabilities (PCPID), HHS.

ACTION: Notice of Meeting.

DATES: Tuesday, October 16, 2012, from 8:30 a.m. to 3:15 p.m. (EST); and Wednesday, October 17, 2012, from 8:30 a.m. to 4:30 p.m. (EST). The meeting will be open to the public.

ADDRESSES: The meeting will be held in Conference Room 800 of the Hubert H. Humphrey Building, U.S. Department of Health and Human Services, 200

Independence Avenue SW., Washington, DC 20201. Individuals who would like to participate via conference call may do so by dialing 888-730-9135, pass code: 6725139. Individuals whose full participation in the meeting will require special accommodations (e.g., sign language interpreting services, assistive listening devices, materials in alternative format such as large print or Braille) should notify MJ Karimi, PCPID Program Analyst, via email at MJ.Karimi@acf.hhs.gov, or via telephone at 202-619-3165, no later than Monday, October 08, 2012. PCPID will attempt to meet requests for accommodations made after that date, but cannot guarantee ability to grant requests received after this deadline. All meeting sites are barrier free, consistent with the Americans with Disabilities Act (ADA), and the Federal Advisory Committee Act (FACA).

Agenda: Committee members will discuss preparation of the PCPID 2012 Report to the President, including its content and format, and related data collection and analysis required to complete the writing of the Report.

Additional Information: For further information, please contact Laverdia Taylor Roach, Senior Advisor, President's Committee for People with Intellectual Disabilities, 200 Independence Avenue SW., Room 637D, Washington, DC 20201. Telephone: 202-205-5970. Fax: 202-260-3053. Email: Laverdia.Roach@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: PCPID acts in an advisory capacity to the

President and the Secretary of Health and Human Services, through the Administration on Intellectual and Developmental Disabilities, on a broad range of topics relating to programs, services and supports for persons with intellectual disabilities. The PCPID Executive Order stipulates that the Committee shall: (1) Provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President concerning the following for people with intellectual disabilities: (A) Expansion of educational opportunities; (B) promotion of homeownership; (C) assurance of workplace integration; (D) improvement of transportation options; (E) expansion of full access to community living; and (F) increasing access to assistive and universally designed technologies.

Dated: September 6, 2012.

Sharon Lewis,

Commissioner, Administration on Intellectual and Developmental Disabilities.

[FR Doc. 2012-22830 Filed 9-14-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0020]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study of Consumer Response to Health Claims and Disclaimers About the Relationship Between Selenium and Risk of Various Cancers

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 October 17, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910—New and title “Experimental Study of Consumer Response to Health Claims and Disclaimers About the Relationship Between Selenium and Risk of Various Cancers.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400T, Rockville, MD 20850, domini.bean@fda.hhs.gov.

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.

Experimental Study of Consumer Response to Health Claims and Disclaimers About the Relationship Between Selenium and Risk of Various Cancers—(OMB Control Number 0910—New)

I. Background

FDA regulates the labeling of food products under the Federal Food, Drug, and Cosmetic Act, as amended by the Nutrition Labeling and Education Act of 1990 (NLEA). NLEA regulations establish general requirements for voluntary health claims in food labeling; health claims are labeling statements that characterize the relationship between a food substance and a disease or health-related condition (21 CFR 101.14(a)(1)). Under the petition process for new health claims (21 CFR 101.70), the petitioner must submit the scientific evidence supporting a proposed health claim to FDA for review. If FDA determines that there is significant scientific agreement (SSA) among experts that the proposed health claim is supported by the totality of publicly available evidence, FDA issues a regulation authorizing the claim (21 CFR 101.14(c) and (d)). Health claims must be “complete, truthful, and not misleading” (21 CFR 101.14(d)(2)(iii)) and must “enable the public to comprehend the information provided and to understand the relative significance of such information in the context of a total daily diet” (21 CFR 101.14(d)(2)(v)).

In a court challenge to FDA’s decision not to authorize four dietary supplement health claims that failed to meet the SSA standard, the U.S. Court of Appeals for the DC Circuit held that the First Amendment does not permit FDA to prohibit health claims that the Agency determines to be potentially misleading unless the Agency also reasonably determines that a disclaimer would not eliminate the potential deception (*Pearson v. Shalala*, 164 F.3d 650 (DC Cir. 1999)). Because the court also held that a health claim is not inherently misleading simply because the evidence supporting it does not reach the SSA level, the decision effectively requires FDA to permit health claims that are backed by credible scientific evidence unless the Agency can demonstrate that the claim would mislead consumers. In response to the court’s decision, FDA issued guidance on an interim review process for health claims that do not meet the SSA standard for the issuance of a regulation authorizing the claim (Ref. 1). These claims, referred to as “qualified health claims” (QHCs), include a disclaimer or other qualifying language to distinguish them from

claims that meet the SSA standard and to prevent consumers from being misled about the level of scientific evidence supporting the claim (Ref. 2). When FDA reviews a QHC petition and determines that the proposed claim is supported by credible evidence and that it can be qualified to prevent consumers from being misled, the Agency issues a letter stating its intent to exercise enforcement discretion for the use of the QHC in food labeling.

In 2003, FDA issued a letter of enforcement discretion for two QHCs for dietary supplements containing selenium (Ref. 3):

Claim 1: “Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.”

Claim 2: “Selenium may produce anticarcinogenic effects in the body. Some scientific evidence suggests that consumption of selenium may produce anticarcinogenic effects in the body. However, FDA has determined that this evidence is limited and not conclusive.”

In 2007, FDA published a notice in the **Federal Register** (72 FR 72738; December 21, 2007) (the 2007 notice) announcing the Agency’s intent to reevaluate these two QHCs, among other health claims. One of the other health claims being reevaluated is the authorized health claim for dietary fat and cancer risk in § 101.73 (21 CFR 101.73). The model health claims in § 101.73(e) use language similar to the “certain cancers” language used in Claim 1 for selenium, as they state that low-fat diets may reduce the risk of “some cancers” or “some types of cancers.” The 2007 notice explained that, during FDA’s reevaluation of the scientific evidence underlying these claims, the Agency also planned to consider whether the claims should be revised to replace generic references to “certain cancers” (or similar language) with the names of specific cancers (e.g., prostate cancer, breast cancer) because each type of cancer is a separate disease with different causes and risk factors (72 FR at 72740).

In 2008, FDA received a petition requesting enforcement discretion for two additional QHCs similar to the ones for which FDA had issued a letter of enforcement discretion in 2003. The basic claim in the first sentence of each proposed QHC was the same as the claim in the first sentence of the corresponding 2003 QHC (“selenium may reduce the risk of certain cancers” and “selenium may produce anticarcinogenic effects in the body,” respectively), but the 2008 petition