

due 90 days after the close of the project period.

VII. Agency Contacts

Program Office Contact: Pam Johnson, 330 C St., SW., Washington, DC 20447, Phone: 202-205-8086, E-mail: pjohnson@acf.hhs.gov.

Grants Management Office Contact: Peter Thompson, Grants Officer, Administration for Children and Families, Children's Bureau, 330 C Street, SW., Room 2070, Washington, DC 20447, Phone: 202-401-4608, E-mail: pthompson@acf.hhs.gov.

VIII. Other Information

Notice: Beginning with FY 2006, the Administration for Children and Families (ACF) will no longer publish grant announcements in the **Federal Register**. Beginning October 1, 2005 applicants will be able to find a synopsis of all ACF grant opportunities and apply electronically for opportunities via: www.Grants.gov. Applicants will also be able to find the complete text of all ACF grant announcements on the ACF Web site located at: <http://www.acf.hhs.gov/grants/index.html>.

Additional information about this program and its purpose can be located on the following Web sites: <http://www.acf.hhs.gov/programs/cb/>.

For general questions regarding this announcement please contact: ACYF Operations Center, The Dixon Group ATTN: Children's Bureau, 118 Q Street, NE., Washington DC 20002-2132, Telephone: 866-796-1591.

Applicants will not be sent acknowledgements of received applications.

Dated: June 8, 2005.

Susan Orr,

Acting Commissioner, Administration on Children, Youth and Families.

[FR Doc. 05-11920 Filed 6-15-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0124]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body

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 July 18, 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 written 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.

Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body—(OMB Control Number 0910-0374)—Extension

Section 403(r)(2)(G) and (r)(3)(C) of the Federal Food, Drug, and Cosmetic

Act (the act) (21 U.S.C. 343(r)(2)(G) and (r)(3)(C)), as amended by the FDA Modernization Act of 1997 (FDAMA), provides that a food producer may market a food product whose label bears a nutrient content claim or a health claim that is based on an authoritative statement of a scientific body of the U.S. Government or the National Academy of Sciences. Under this section of the act, a food producer that intends to use such a claim must submit a notification of its intention to use the claim 120 days before it begins marketing the product bearing the claim. In the **Federal Register** of June 11, 1998 (63 FR 32102), FDA announced the availability of a guidance entitled "Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body." The guidance provides the agency's interpretation of terms central to the submission of a notification and the agency's views on the information that should be included in the notification. The agency believes that the guidance will enable food producers to meet the criteria for notifications that are established in section 403(r)(2)(G) and (r)(3)(C) of the act. In addition to the information specifically required by the act to be in such notifications, the guidance states that the notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. FDA intends to review the notifications the agency receives to ensure that they comply with the criteria established by the act.

In the **Federal Register** of April 8, 2005 (70 FR 18031), FDA published a 60-day notice requesting public comment on the information collection provisions. One comment was received that was not relevant to the information collection.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN ¹

Section of the act/basis of burden	No. of respondents	No. of responses per respondent	Total annual responses	Hours per response	Total hours
403(r)(2)(G) (nutrient content claims)	1	1	1	250	250
403(r)(3)(C) (health claims)	2	1	2	450	900

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

Section of the act/basis of burden	No. of respondents	No. of responses per respondent	Total annual responses	Hours per response	Total hours
Guidance for notifications	3	1	3	1	3
Total					1,153

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 health claims, nutrient content claims, and other similar notification procedures that fall under the agency's jurisdiction. Because the claims are based on an authoritative statement of certain scientific bodies of the Federal Government or the National Academy of Sciences or one of its subdivisions, FDA believes that the information submitted with a notification will either be provided as part of the authoritative statement, or readily available as part of the scientific literature to firms wishing to make claims. Presentation of a supporting bibliography and a brief balanced account or analysis of this literature should be fairly straightforward.

Dated: June 9, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-11860 Filed 6-15-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0216]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Humanitarian Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for Humanitarian Use Devices.

DATES: Submit written or electronic comments on the collection of information by August 15, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the

information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices: Humanitarian Use Devices—21 CFR Part 814 (OMB Control Number 0910-0332)—Extension

This collection implements the humanitarian use device (HUD) Provision under section 520(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(m)) and 21 CFR part 814, subpart H. Under section 520(m) of the act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the act (21 U.S.C. 360d and 360e) provided that the device do the following: (1) Is used to treat or diagnosis a disease or condition that affects fewer than 4,000 individuals in the United States; (2) would not be available to a person with such a disease or condition unless the exemption is granted, and there is no comparable device, other than another HUD approved under this exemption, available to treat or diagnose the disease or condition; and (3) the device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The information collection will allow FDA to determine whether to do the following: (1) Grant HUD designation of a medical device, (2) exempt a HUD from the effectiveness requirements in sections 514 and 515 of the act provided that the device meets requirements set forth in section 520(m) of the act, and (3) grants marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making those determinations. Also, this information enables FDA to determine whether the holder of a HUD is in compliance with the HUD requirements.