ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
DD Council Program Performance Report	55	1	44	2,420

Estimated Total Annual Burden Hours: 2,420.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: August 10, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–21787 Filed 8–12–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0389]

Agency Information Collection Activities: Proposed Collection; Comment Request; Notification of a Health Claim or a Nutrient Content Claim Based on an Authoritative Statement

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, 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 the submission of notifications of health claims or nutrient content claims based on authoritative statements of scientific bodies. This action is in response to provisions of the FDA Modernization Act of 1997 (FDAMA). In the **Federal Register** of August 6, 1998 (63 FR 42053), FDA published a notice announcing OMB's approval of this collection of information (OMB control number 0910—0374). Since this was an emergency approval that expires on November 30, 1998, FDA is following the normal PRA clearance procedures by issuing this notice.

DATES: Submit written comments on the collection of information by October 13, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, 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: Margaret R. Schlosburg, Office of Information Resources Management (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 below.

With respect to the following collection of information, FDA invites comments on: (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.

Notification of a Health Claim or a Nutrient Content Claim Based on an Authoritative Statement (OMB Control Number 0910–0347—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 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 Federal Government or the National Academy of Sciences. Under these sections 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.

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 a notification. 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 estimates the burden of this collection of information as follows:

TABLE 1.— ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Guidance for Notifications	12	5	60	1	60

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

The agency believes that this 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 during the interim period while the agency is initiating notice-and-comment rulemaking in this matter. FDA intends to review the notifications it receives to ensure that they comply with the criteria established for them by the act.

These estimates are based on FDA's experience with health claims and nutrient content claims and with other similar notification procedures that fall under its jurisdiction. Because the claims are based on authoritative statements 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 be either provided as part of the authoritative statement or readily available to firms wishing to make claims.

The hour burden estimates contained in Table 1 of this document are for the information collection requests in the guidance only and do not include statutory requirements specifically mandated by the act.

Dated: August 6, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–21796 Filed 8–12–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Hematology and Pathology Devices Panel and the Immunology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Joint meeting of the Hematology and Pathology Devices Panel and the Immunology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 4, 1998, 9:30 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Veronica J. Calvin, Center for Devices and Radiological Health (HFZ09440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 30109594091243, or FDA Advisory Committee Information Line, 10980009741098138 (30109443090572 in the Washington, DC area), code 12515. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for an immunohistochemical device indicated for the detection of HER2 overexpression in breast cancers.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by August 21, 1998. Oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 a.m. Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission or topic before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 21, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 6, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–21736 Filed 8–12–98; 8:45 am]

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