

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 BURDEN¹

	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.

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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.

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