## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98D–0389]**

### Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing 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 is intended to provide information regarding 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).

**DATES:** Written comments on agency guidance documents may be submitted at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance entitled ''Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body'' to the Office of Food Labeling (HFS–150), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent. Alternatively, you may fax your request to 202–205–5494. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance. Submit written comments on this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Constance B. Henry, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

**SUPPLEMENTARY INFORMATION:** FDA is announcing 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 agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). The guidance entitled ''Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body'' is issued as a level 1 guidance consistent with GGP's. It may be utilized upon issuance because it is needed to help effect the implementation of the new statutory provisions of FDAMA.

This guidance document represents the agency's current thinking on the submission of notifications under sections 303 and 304 of FDAMA (new section 403(r)(3)(C) and (r)(2)(G) of the Federal Food, Drug, and Cosmetic Act). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This guidance document contains a collection of information that requires clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995. In a notice published elsewhere in this issue of the **Federal Register**, FDA is announcing that this collection of information has been submitted to OMB for emergency processing. The notice also solicits comments on the collection of information.

An electronic version of the guidance entitled ''Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body'' is also available on the Internet at ''http://www.cfsan.fda.gov/~dms/guidance.html''.

Dated: June 5, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98N–0320]**

### Agency Emergency Processing Request Under OMB Review

**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 emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns 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).

**DATES:** Submit written comments on the collection of information by June 22, 1998.

**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: Desk Officer for FDA. 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:**

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**

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 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.

Elsewhere in this issue of the **Federal Register**, FDA is announcing 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 | No. of Responses per Respondent | Total Annual Responses | Hours per Response | Total Annual 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 sections 403(r)(2)(G) and 403(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.

FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13. The information is needed immediately to implement FDAMA, and it is essential to the agency's mission of protecting and promoting the public health. The use of normal clearance procedures would be likely to result in the prevention or disruption of this collection of information.

Dated: June 3, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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