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Part III

Department of Health and Human Services

Food and Drug Administration

Guidance for Industry: Notification of a Health Claim or Nutrient
Content Claim Based on an Authoritative Statement of a Scientific Body
and Agency Emergency Processing Request Under OMB Review; Notices

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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/difference>dms/guidance.html>.

Dated: June 5, 1998.
William K. Hubbard,
Associate Commissioner for Policy Coordination.
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