REGISTRATION: Send registration information (including name, title, firm name, address, telephone, and fax number), via fax or e-mail to the contact person by Friday, September 4, 1998.

If you need special accommodations due to a disability, please contact the contact person at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Manufacturers in the Pacific Region, who employ biotechnology in the production of FDA regulated products will be able to identify and evaluate opportunities for implementing a partnership approach with FDA. In the Federal Register of April 20, 1995 (60 FR 19753), FDA announced that a series of Grassroots Regulatory Partnerships Meetings would be held to further the President's initiative. FDA's goal at this meeting is to ''listen'' to concerns and ideas of the biotechnology industry, and to identify next steps for the agency.

There is no registration fee for this meeting. However, registration is required. Early registration is recommended because of space limitations and the need to send information about the meeting format to each registrant. You will be asked to identify the subject area breakout session in which you prefer to participate. To permit the greatest number of firms to attend, each company registering for this meeting should send no more than two representatives.

Dated: July 29, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20955 Filed 8–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0389]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

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: In the Federal Register of June 11, 1998 (63 FR 32102), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0374. The approval expires on November 30, 1998.

Dated: July 29, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20957 Filed 8–5–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0519]

Draft Modifications To Devices Subject To Premarket Approval—The PMA Supplement Decision Making Process; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Modifications To Devices Subject To Premarket Approval—The PMA Supplement Decision Making Process.'' This draft guidance is neither final nor is it in effect at this time. The draft guidance includes a flowchart model that could be used by premarket approval application (PMA) holders in their decisionmaking to analyze whether certain changes in a device affect the safety or effectiveness of the device, and therefore, require submission of a new PMA, PMA supplement, alternate submission to a PMA supplement, annual report or documentation in the PMA holders' files on the device.

DATES: Written comments concerning this draft guidance must be received by November 4, 1998.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Modifications To Devices Subject To Premarket Approval—The PMA Supplement Decision Making Process'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Written comments concerning this draft guidance must be submitted to the Dockets Management Branch, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In January 1997, FDA released a guidance document entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device.'' This document was an effort to clarify current practice and FDA's expectations regarding the process used to determine whether a change to a class I or II device or to a class III device for which premarket approval had not yet been required under section 515(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(b)), required submission of a new 510(k).

Class III devices subject to premarket approval requirements under section 515 of the act were not addressed by that document and the PMA regulation, part 814 (21 CFR part 814), provides only general criteria for determining whether a PMA supplement is required for a particular device change. FDA's process of developing specific guidance on submission of PMA supplements coincided with FDA reengineering activities, including the CDRH effort to streamline the PMA supplement process within the context of the existing premarket approval regulation (part 814).

The draft guidance has been developed to aid PMA holders who