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]

BILLING CODE 4160–01–F

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

intend to modify their device and are in the process of deciding the type of documentation and/or submission necessary for that particular modification. The draft guidance concerning changes to an existing device is intended to complement, not supplant, existing guidances on the premarket approval process. It is not intended to apply to combination products, such as drug/device or biologic/device combinations.

This draft guidance incorporates three separate flowcharts for in vitro diagnostic devices (IVD's). These flowcharts cover changes in technology or performance, change assessment, and materials changes for IVD's. This draft guidance applies to in vitro diagnostic devices regulated by the CDRH and application of this guidance to in vitro diagnostic devices regulated under premarket approval by the Center for Biologics Evaluation and Research (CBER) should be discussed with CBER.

The types of modifications addressed in the draft guidance include changes in device design, device labeling, device materials, and the manufacturing process for the device. This draft guidance can also be applied to situations when a legally marketed device is the subject of a recall and a change is indicated to assure the safety and effectiveness of the device.

When contemplating changes to any approved device, PMA holders should use the flowchart for ''each'' type of proposed change. In those circumstances where the proposed change is not addressed in the flowchart or in a device-specific guidance document, PMA holders are encouraged to contact the Office of Device Evaluation (ODE) in CDRH for additional information.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on modifications to devices which are subject to premarket approval. This draft guidance 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 applicable statute, regulations, or both.

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). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Modifications To Devices Subject To Premarket Approval—The PMA Supplement Decision Making Process'' via your fax machine, call the CDRH Facts–On–Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (855) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes ''Modifications To Devices Subject To Premarket Approval—The PMA Supplement Decision Making Process,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

IV. Comments

Interested persons may, on or before November 4, 1998, submit to Dockets Management Branch (address above) written comments regarding this draft guidance. 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 draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 22, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–20958 Filed 8–5–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–2567]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Statement of Deficiencies and Plan of Correction and Supporting Regulations in 42 CFR 488.18, 488.26, and 488.28; Form No.: HCFA–2567 (OMB# 0938–0391); Use: This Paperwork package provides information regarding the form used by the Medicare, Medicaid, and the Clinical Laboratory Improvement Amendments (CLIA) programs to document a health care facility's compliance or noncompliance (deficiencies) with regard to the Medicare/Medicaid Conditions of Participation and Coverage, the requirements for participation for Skilled Nursing Facilities and Nursing Facilities, and for certification under