Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Cathy Groupe at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 20, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7–5506 Filed 3–26–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0083]

Draft Guidance for Industry and Food and Drug Administration Staff; Modifications to Devices Subject to Premarket Approval—The Premarket Approval Supplement Decision-Making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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Modifications to Devices Subject to Premarket Approval (PMA)—The PMA Supplement Decision-Making Process.'' This draft guidance is intended to help the regulated industry determine whether submitting a PMA supplement or other notification to FDA is required for class III devices subject to PMA. This draft guidance is not final nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by June 25, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Modifications to Devices Subject to Premarket Approval (PMA)—The PMA Supplement Decision-Making Process'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For general questions: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4010.

For questions about the 30-day notice program or regarding manufacturing site changes: Christy Foreman, Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 240–276–0120.

For biologics issues: Leonard Wilson, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance is intended to help the regulated industry determine whether submitting a PMA supplement or other notification to FDA is required for class III devices subject to PMA. FDA developed this draft guidance to address modifications to device design, device labeling, and the device manufacturing process. This guidance also can be applied when a legally marketed class III device is the subject of a recall or field corrective action and the manufacturer needs to change the device to assure its safety and effectiveness. This draft guidance is intended to apply to the device portion of combination products such as drug/device or biologic/device combinations.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on modifications to devices subject to PMA applications. 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 and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''Modifications to Devices Subject to Premarket Approval (PMA)—The PMA Supplement Decision-Making Process,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1584 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520) (the PRA). The collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing PMA applications (21 CFR part 814, OMB control number 0910–0231).

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that

individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 16, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–5572 Filed 3–26–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Independent Evaluation of the Substance Abuse Prevention and Treatment Block Grant Program—NEW

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), Division of State and Community Assistance administers the Substance Abuse Prevention and Treatment Block Grant (SAPT BG) in collaboration with the Center for Substance Abuse Prevention (CSAP), Division of State Programs. The Substance Abuse Prevention and Treatment Block Grant is funded by Congress to provide monies to States, Territories, and one Native American Tribe for the purpose of planning, carrying out, and evaluating activities to prevent and treat substance abuse and other allowable activities. The SAPT BG constitutes approximately 40 percent of all States budgets for substance abuse prevention and treatment services and activities, and is the primary Federal source of funding. States have flexibility in determining how funds should be allocated, but there are specific set-aside and maintenance of effort requirements that must be met in order to receive funding. These requirements, introduced by both the ADAMHA Reorganization Act of 1992 and the Children's Health Act of 2000, are listed below:

TABLE 1.—SAPT BG SET-ASIDE PROVISIONS [a]

Category	Set-aside provision
Prevention and treatment activities regarding alcohol.	Not less than 35 percent of SAPT BG funding.*
Prevention and treatment activities regarding other drugs.	Not less than 35 percent of SAPT BG funding.*
Primary prevention programs	Not less than 20 percent of SAPT BG funding.
Pregnant women and women with dependent children.	Not less than amount equal to expenditure in FY1994.
Tuberculosis services	No set amount but services must be provided to receive SAPT BG funds.
HIV services [b]	No more than 5 percent increase over State allotment for HIV services in FY 1991.
Prohibition of sale of tobacco to individuals under age of 18 (Synar amendment).	State must enforce law against sale of tobacco to underage individuals to receive SAPT BG funds—noncompliance leads to a 10 percent reduction in funds the first applicable fiscal year; 20 percent, the second year; 30 percent, the third year; and 40 percent, the fourth year.
Maintenance of effort (MOE) for State expenditures.	State will maintain funding at no less than the average level of expenditures for the 2 years preceding the fiscal year for which the State is applying.
Administrative expenses	Limited to 5 percent of SAPT BG funding.

[a] These set-asides shown in this table were included in the 1992 SAPT BG authorizing legislation 42 U.S.C. 300x–21 to 42 U.S.C. 300x–62). In the Children's Health Act of 2000 (Pub. L. 106–310) Sec. 3303(a)(1)), however, the set-asides marked with asterisks were removed.

[b] For designated States whose rate of AIDS cases is 10 or more per 100,000 individuals as confirmed by the Centers for Disease Control and Prevention.

In addition to the set-asides, the SAPT BG Program has identified 17 goals which must be met by States in order to receive this Federal funding:

TABLE 2.—FEDERAL GOALS FOR THE SUBSTANCE ABUSE PREVENTION AND TREATMENT BLOCK GRANT

GOAL #1: Continuum of substance abuse treatment services.	The State shall expend block grant funds to maintain a continuum of substance abuse treatment services that meet these needs for the services identified by the state (see 42 U.S.C. 300x–21(b) and 45 CFR 96.122(f)(g)).
GOAL #2: Spending on primary prevention programs.	The State agrees to spend not less than 20 percent on primary prevention programs for individuals who do not require treatment for substance abuse, specifying the activities proposed for each of the six strategies (see 42 U.S.C. 300x–22(b)(1) and 45 CFR 96.124(b)(1)).