

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier D. Hawkins

[Docket No. FDA-2007-D-0025] (formerly Docket No. 2007D-0083)

Guidance for Industry and the Food and Drug Administration; Modifications to Devices Subject to Premarket Approval—the Premarket Approval Supplement Decisionmaking Process; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Modifications to Devices Subject to Premarket Approval (PMA)—the PMA Supplement Decision-Making Process.” The purpose of this guidance is to help industry determine the type of regulatory submission that may be required when a device subject to PMA is modified.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the 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 (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850; or to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite

200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at 240–276–3151. The guidance document may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. 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.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4010; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA developed this guidance to address modifications to devices subject to PMA applications, including changes 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.

In the **Federal Register** of March 27, 2007 (72 FR 14282), FDA invited interested persons to comment on its draft guidance document entitled, “Modifications to Devices Subject to Premarket Approval (PMA)—the PMA

Supplement Decision-Making Process.” The five general categories of comments received regarding the draft guidance are as follows: (1) Requests for a clearer interpretation of the regulations as to when a supplement is necessary (i.e., when a change to a device impacts or could impact safety and/or effectiveness); (2) requests for a detailed flowchart that would identify the type of supplement to be submitted based on any specific change for any device; (3) requests for specific definitions for some terms, such as “substantial clinical data,” “significant change,” and “limited confirmatory clinical data;” (4) requests for FDA to include 30-day supplements within the scope of the guidance; and (5) requests for additional examples for many supplement types, as well as for periodic reports. We considered all of the comments and revised the guidance when appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the agency’s current thinking on “Modifications to Devices Subject to Premarket Approval (PMA)—the PMA Supplement Decision-Making Process.” 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 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 CBER Internet site at <http://www.fda.gov/cber/guidelines.htm> or on the Division of Dockets Management Internet site at <http://www.regulations.gov>.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The information collection provisions in 21 CFR part 814, subpart B (Premarket Approval Applications (PMAs)) in this guidance have been approved under OMB control number 0910–0231. This approval expires November 30, 2010.

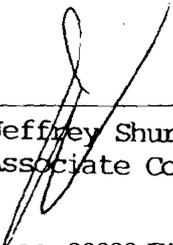
V. Comments

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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: 12/5/08
December 5, 2008.

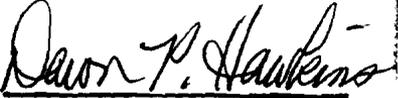


Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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