

Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will review any comments we receive and revise the guidance document when appropriate.

Dated: November 19, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D-0173]

Guidance for Industry and FDA Staff: Expedited Review of Premarket Submissions for Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Expedited Review of Premarket Submissions for Devices." This guidance describes how the agency is applying the statutory criteria and the additional criteria identified in a letter accompanying the user fee legislation to meet the new performance goals for expedited premarket approval applications (PMAs). This guidance also describes FDA's expedited review procedures for premarket notification submissions (510(k)s), product development protocols (PDPs), and *de novo* classification actions. This guidance document is immediately in effect, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

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 on a 3.5" diskette of the guidance document entitled "Expedited Review of Premarket Submissions for Devices" 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 two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. 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 questions regarding PMAs: Thinh Nguyen, Center for Devices and Radiological Health (HFZ-402), 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2186.

For questions regarding 510(k)s, including the evaluation of automatic class III designation: Heather Rosecrans, Center for Devices and Radiological Health (HFZ-402), 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190.

For questions regarding devices regulated by the Center for Biologics Evaluation and Research: Sayah Nedjar, Center for Biologics Evaluation and Research (HFM-380), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-3524.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 31, 1998 (63 FR 15427), FDA issued a guidance entitled "PMA/510(k) Expedited Review Guidance for Industry and the Center for Devices and Radiological Health (CDRH) Staff" in which the agency outlined its interpretation of the statutory criteria for expedited review of PMAs. No comments were received on the guidance.

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), was signed into law on October 26, 2002. Performance goals for expedited PMAs were referenced in the statute and apply to such applications when newly identified criteria are met by the applicant (<http://www.fda.gov/cdrh/mdufma/pgoals.html>). The new guidance entitled "Expedited Review of Premarket Submissions for Devices" supersedes and replaces the 1998 guidance document and explains the procedures that FDA intends to use to review and track expedited PMA applications against the MDUFMA performance goals when the PMA applicant meets the additional criteria. The new guidance also explains the procedures that FDA plans to use to

expedite the review of PDPs, 510(k)s, and *de novo* classification actions.

Because the agency had to implement its program for meeting the expedited review performance goals as soon as the new law became effective, FDA has determined, under §10.115(g)(2) (21 CFR 10.115(g)(2)), that it was not feasible to obtain comments before issuing this guidance. Therefore, in accordance with FDA's GGP procedures, FDA is issuing this as a level 1 guidance that is immediately in effect and will accept comments on the guidance at any time.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (§10.115). The guidance represents the agency's current thinking on procedures for expedited review of PMAs, given the enhanced PMA performance goals for expedited applications. The guidance also discusses the expedited review procedures for 510(k)s, PDPs, and *de novo* classification actions. 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 statutes and regulations.

III. Electronic Access

To receive "Expedited Review of Premarket Submissions for Devices" by fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (108) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. 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>.