

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0492]

Display Date 12-27-07 3:08pm
Publication Date 1-2-08
Certifier L. CLAWSON
DDM

Guidance for Industry and Food and Drug Administration; Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements.” The purpose of this guidance document is to recommend an interactive premarket review process for these submissions that is designed to expedite FDA’s review of device applications while continuing to assure device safety and effectiveness, in accordance with the goals of the Food and Drug Administration Amendments Act of 2007 (FDAAA).

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

ADDRESSES: Submit written requests for single copies of the guidance document entitled “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements” 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-

ch 0753

2007D-0492

NAD 1

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 either <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Samie Allen, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4013.

SUPPLEMENTARY INFORMATION:

I. Background

In the letter from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate setting out the goals of the Medical Device User Fee Amendments of 2007 (MDUFA) (see section 201(c) of FDAAA), dated September 27, 2007, FDA committed to developing a guidance document that describes an interactive review process between FDA and industry for specific medical device premarket submissions. While FDA committed to developing an interactive review process only for premarket notification submissions (510(k)s), premarket approval applications (PMAs), and PMA supplements, the agency believes that medical device Biologic License Applications (BLAs) could also benefit from such a process. Therefore, the guidance document also applies to medical device BLAs and BLA supplements.

The goal of the interactive review process is to improve the timeliness of the review process for 510(k)s, PMAs, PMA supplements, BLAs and BLA supplements. FDA expects that the interactive review process will result in prompt approvals and clearances of medical devices and thereby improve the public health. FDA intends to reassess the interactive review process on a regular basis to determine whether it is meeting its intended objectives. When necessary, changes will be implemented to improve the efficiency of this process.

FDA is making this guidance document immediately in effect because prior public participation was not feasible or appropriate. In the letter described in section 201(c) of FDAAA that sets out the goals of MDUFA, FDA committed to developing, within 3 months of the date of FDAAA's enactment, a guidance document that describes an interactive review process. The interactive review process supports a less burdensome approach to the premarket review process that is consistent with public health.

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 the interactive review process for premarket medical device submissions. 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 "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA

Supplements,” 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 1655 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>.

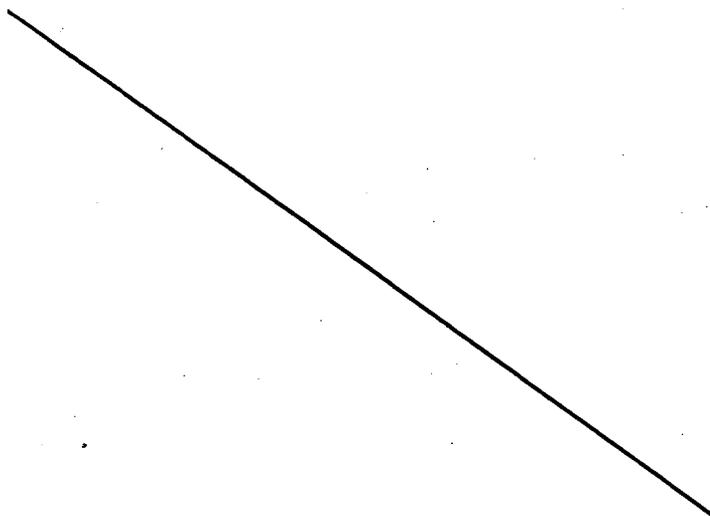
IV. Paperwork Reduction Act of 1995

This 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 (44 U.S.C. §§ 3501-3520) (the PRA). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910-0231; and the collections of information in 21 CFR part 601, subpart A, have been approved under OMB control number 0910-0338.

V. Comments

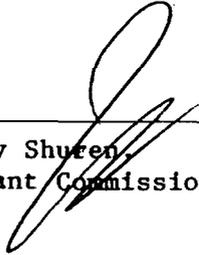
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be 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 in January 2008, the FDA website is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When



the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

Dated: 12/26/07
December 26, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL
