

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0348]

Draft Guidance for Industry and Food and Drug Administration Staff; Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Procedures for Handling Post-Approval Studies Imposed by PMA Order.” The draft guidance is designed to assist the Center for Devices and Radiological Health (CDRH) and sponsors to meet their responsibilities to track post-approval studies (sometimes called Condition of Approval Studies) that are mandated for market approval of medical devices.

DATES: Submit written or electronic comments on this draft guidance by [*insert date 60 days after date of publication in the **Federal Register***].

ADDRESSES: Submit written requests for single copies on a 3.5” diskette of the draft guidance document entitled “Procedures for Handling Post-Approval Studies Imposed by PMA Order” to the Division of Small Manufacturers, International, and Consumer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 301-443-8818. See

the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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: Steven H. Chasin, Office of Surveillance and Biometrics, Division of Postmarket Surveillance, Center for Devices and Radiological Health (HFZ-500), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3674

SUPPLEMENTARY INFORMATION:

I. Background

The draft guidance is designed to assist sponsors and CDRH to oversee post-approval studies. These studies are oftentimes mandated at the time the Center approves a Premarket Approval Application (PMA) to address additional concerns. This guidance aims to assure that:

- Sponsors submit clear, consistent and timely study reports;
 - CDRH can track the status of the studies;
 - CDRH staff reviews the studies and holds discussions with the sponsors in a timely manner;
 - CDRH stakeholders can quickly learn about the status of these studies;
- and
- CDRH can take appropriate and timely action based on study results.

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 "Procedures for Handling Post-Approval Studies Imposed by PMA Order." 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

To receive "Procedures for Post-Approval Studies Imposed by PMA Order" 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 (1516) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft 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>.

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 collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket approval 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 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: September 9, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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