Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies – for Use by CDRH and Industry

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PMA Staff, Office of Device Evaluation

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Until May 26, 1998, comments and suggestions regarding this document should be submitted to Docket No. 98D-0079, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 12420 Parklawn Drive (HFA-305), Room 1-23, Rockville, MD 20857. Such comments will be considered when determining whether to amend the current guidance.

After May 26, 1998, comments and suggestions may be submitted at any time for Agency consideration to Kathy M. Poneleit or Lisa C. Fisher, 9200 Corporate Blvd, HFZ-402, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Kathy M. Poneleit or Lisa C. Fisher at 301-594-2186.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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Background/Purpose

The FDA Modernization Act of 1997 (Pub. L. 105-115) added new section 515(d)(3) to the FD&C Act. This section requires FDA, upon written request, to meet with the applicant no later than 100 days after the receipt of a PMA application that has been filed. The purpose of the meeting is to discuss the review status of the application. With the concurrence of the applicant, a different schedule may be established. The section also states that, prior to the meeting, FDA is to inform the applicant in writing of any identified deficiencies and what information is required to correct those deficiencies. FDA must also promptly notify the applicant if it identifies additional deficiencies or any additional information required to complete agency review. This guidance[1] describes the procedures to be used to implement this interactive review provision. The guidance applies to original PMA applications received by FDA on or after February 19, 1998. While FDA will honor requests for review status meetings from applicants with pending submissions (i.e., PMA's submitted prior to February 19, 1998), the timing for such meetings will vary depending on the review status of the individual application.

The Meeting Request

The meeting request should be submitted with the PMA or as an amendment to the PMA no later than 70 days from FDA receipt of the PMA accepted for filing or 70 days from submission of the amendment making the PMA filable ("filing date"). This 30 day lead time is needed to allow FDA sufficient time to schedule the meeting. In the written request, the applicant should specify the type of meeting desired, e.g., face-to-face, teleconference, or videoconference, provide a list of the persons who will attend for the company, and identify several possible dates for the meeting. After a letter filing the application has been issued, the reviewing division will contact the applicant to set up the meeting if requested. As provided by the statute, FDA and the applicant may, by mutual consent, establish a different time for the "day 100" meeting.

Meeting Preparation and Documentation, Follow-Up

1. There will be identified to the applicant at the time of filing review a contact person on the review team who will ordinarily be the PMA project manager. The person will be responsible for coordinating the project, the interactive review meetings, and status reports.

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2. FDA will provide the applicant with a written description of any deficiencies in the application that, at that point, have been identified based on an interim review of the entire application and will identify the information that is required to correct those deficiencies approximately 90 days from the filing date of the PMA. Minor deficiencies may be identified as well. This early communication will occur whether or not the applicant requests a day 100 meeting. The letter should be faxed to the applicant either by day 90 in the review cycle or at least 10 days prior to any day 100 meeting to facilitate a meaningful dialogue with the applicant.

3. The relevant core review team, Branch Chief, and Division Director or Deputy Director will attend the meeting with the applicant. Others attendees from FDA will include Program Operations Staff (POS) and Office management as appropriate.

4. During the meeting the following may occur:

    - a general discussion of identified issues and discussion of remedial actions,
    - a discussion of an action plan with estimated dates of completion,
    - a discussion of FDA estimated timetables for review completion,
    - identification of the need for panel involvement,
    - a discussion of possible premarket versus postmarket requirements.

5. Draft minutes of the meeting will be distributed to all attendees and the review team leader will provide the final minutes to the attendees, POS, and the administrative record.

6. After the day 100 meeting, FDA will continue to communicate promptly with the applicant via teleconference, fax, videoconference, etc., or in writing the status of the review and what if any additional information has been identified that is required to achieve completion of the review and final action on the application. This continued communication will occur at least every 4 weeks using any of the above methods until the review is completed. Minutes or copies of letters of all such interactions, including teleconferences and videoconferences, will be made a part of the administrative record.