Document Review Processing #I91-1 (blue book memo) (Text Only)

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer 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, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

Integrity Memorandum #I91-1

Director, Office of Device Evaluation(HFZ-400)

Document Review Processing (Revised)

ODE Review Staff

Introductory Note

The Document Review Processing guidance memorandum, I91-1, was originally issued on May 29, 1991. In that memorandum we stated that the guidance might be modified, depending upon comments received during the training sessions conducted on the subject. This memorandum is a revision of I91-1 which is based on comments made during the training session on the original Blue Book Memorandum.

Purpose

The purpose of this memorandum is to reaffirm the basic principle within ODE that we will attempt to initiate the review of documents on the basis of their dates of submission, i.e., we will attempt to review first the documents that were received first. There will, however, be many exceptions to this principle and these are discussed below. Nevertheless, our underlying goal is to maintain a review process that is fair and without preferential treatment for any applicant.

This guidance sets forth the principles and procedures that are to be applied by individual reviewers to the sequencing and the review of major documents submitted to ODE. This sequencing has to be done on the individual reviewer basis for a number of practical reasons. Each reviewer has a different amount of experience and his or her own pace at which reviews can

be completed. Furthermore, the complexity of the documents under review will vary from reviewer to reviewer. These factors would make it virtually impossible to sequence the review of documents among reviewers.

This guidance complements**Integrity Memorandum #I90-2 (/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313368.pdf)**, entitled "Assignment of Review Documents", which sets forth procedures for the assignment of review documents(PMAs, PMA supplements and amendments, IDEs, IDE supplements and amendments, and 510(k)s) to ODE staff. It also covers reassignment of such documents from primary reviewers to other reviewers. This guidance memorandum and #I90-2 are designed to assure that submissions are assigned and reviewed in a fair and equitable manner.

The principles and procedures set forth in this memorandum constitute general guidance on the sequencing of document reviews. It would be impossible to identify and cover every possible situation that might arise. Thus, reviewers should exercise reasonable judgment in applying this guidance to day-to-day operations. If a reviewer is uncertain on how to handle a specific situation, the reviewer should consult with his or her supervisor. Depending upon the circumstances surrounding a specific submission, a supervisor may modify the sequencing of that submission, provided it is done with the concurrence of the division director or the associate division director.

Similarly, if a reviewer is working on a long and arduous submission, it may be necessary for the reviewer to change occasionally from that submission to another submission in order to maintain a high level of acuity and to avoid the loss of effectiveness. The implementation of workload management is reasonable and, at times, intellectually necessary.

General Principles

Two principles are involved. The first concerns the sequencing of reviews among the various categories of review documents that a reviewer may have. The seven categories of review documents are listed below. For example, a reviewer may have to decide whether to work first on an IDE or PMA or 510(k), etc. Making this decision does not depend upon the incoming date of the applications. This sequencing will be necessary because reviewers have more review documents than they can complete within a due date. Thus, reviewers should arrange their document reviews so they can meet as many due dates as possible. Among the various types of submissions, e.g., PMAs versus 510(k)s versus IDEs, it is often necessary for reviewers to initiate or complete the review of a 510(k) or IDE before initiating or completing the review of a PMA that was submitted earlier. For example, if a reviewer were to work exclusively on a PMA from the time of its receipt until it were completed, the due dates on many 510(k)s or IDEs might not be met. On the other hand, if work on the PMA were suspended to allow completion of some IDEs or 510(k)s, more due dates would be met, even if the due date on the PMA is missed. This is an appropriate scheduling of the workload, unless there were some overriding public health reason that would take precedence over any applicable due dates.

The second general principle deals with the sequencing of reviews within each of the review categories, as identified below. As a general principle, reviewers should initiate the review of applications within each category, e.g., IDEs or 510(k)s, in the order of their earliest current due date. The due date is the date by which a review should be completed to meet the time permitted for the review of such documents under the Food, Drug, and Cosmetic Act or under the policies of this office. This due date is a variable that will change if a document is put on hold. Reviewers should keep informed of the current due dates for the documents under their review by consulting the tracking sheets accompanying their documents or through the division or office databases.

Exceptions

The following situations are frequently occurring circumstances that require or permit deviation from the general principle for the sequencing of document reviews within each category, as set forth above.

- Documents covered by Guidance Memorandum K86-1, "Expedited Review," should be reviewed on an expedited basis as provided in that memorandum.
- For purposes of work efficiency, we will complete the review of any application as soon as possible and without regard for its due date if work on that application does not interfere significantly with work on applications with an earlier due date. For example, a reviewer may be working on multiple submissions at the same time. To promote efficiencies, reviewers may complete the review of an easy submission that came in after a more complex and time consuming submission. In such cases, the subsequently received submission would not be held up until the first submission is ready for a final decision. We will issue a final decision on any submission that is ready at the time it is reviewed. Also, if a reviewer receives a resubmission with an earlier due date than the due date on a submission under active review, it would be sufficient to stop work on the active submission if the work on that submission would have to be repeated. In such a case, the work on the active submission should be completed before work on the resubmission is initiated. Thus, reviewers should not feel they have to refigure their queues every day, which would result in lost review time.
- For the purpose of efficiently completing "easy" submissions, reviewers may find it advantageous to set aside a specific time period each week during which they will complete the review of these submission. "Easy" submissions are those for which the file is complete, i.e., it is not necessary to obtain any clarifications prior to completion of the review; there are no new or complex issues involved; and completion of the review will not interfere with other submissions having an earlier current due date.

Categories of Submissions

These procedures apply to the following seven categories of submissions reviewed by ODE:

- IDEs
- IDE amendments
- IDE supplements
- 510(k)s
- PMAs
- PMA supplements
- PMA filing reviews

Specific Guidance by Category. The following guidance applies to specific categories of review documents and deals primarily with the establishment of due dates within the category.

1. IDE Reviews.

   Reviewers should be looking at their IDEs, IDE amendments, and IDE supplements to see if there are applications that can be completed without interfering with the review of submissions with an earlier due date. If found, such applications should be completed as soon as possible.

2. 510(k) Reviews.

   A. 510(k)s in General. Although a manufacturer may not market the device subject to a pending 510(k) until FDA makes a finding of substantial equivalence, we intend to maintain, to the extent possible, a 90 day turn-around time for these actions. Reviewers should be looking at their 510(k) workload to see if there are submissions that can be completed without interfering with the review of submissions with an earlier due date. If found, such 510(k)s should be completed as soon as possible.

   B. 510(k)s Requiring Simple Clarification. During the review of any 510(k), the clarification of simple questions or deficiencies that do not require the submission of an amendment and that can be handled through a telephone call will not affect what we consider to be the due date of the 510(k).

   C. 510(k)s Requiring Amendments. If deficiencies are found that cannot be taken care of through a telephone conversation, an amendment will be required. In such cases, the review clock will be suspended and the 510(k) will be put on hold. Upon receipt of an amendment, its 90 day clock will be reset and a new due date established. This would apply to any amendment received for a 510(k). For purposes of this guidance, any written document submitted for a 510(k), whether requested by ODE or submitted voluntarily by the manufacturer, that contains substantive information that relates to the determination of substantial equivalency, is considered to be an amendment. On the other hand, general correspondence or correspondence related to collateral matters, such as whether a summary or certification has been filed as available, would not be considered an amendment.

3. PMA Reviews.

A. Filing Reviews. There are multiple reviews a PMA may undergo. The first review is a filing review. Filing reviews should be completed within 45 days of receipt of the PMA in the Document Mail Center. (For further information on prefiling decision-making see **ODE Guidance Memorandum #P90-2 (ssLINK/ucm089430.htm)**, entitled, "PMA Filing Decisions".) Once a PMA is filed, the filing date will be used to determine the due date, except as otherwise noted below.

B. PMAs in General. Reviewers should be looking at their PMA workload to see if there are applications that can be completed without interfering with the review of applications with an earlier due date. If found, such PMAs should be completed as soon as possible.

C. PMAs with a Minor Deficiency. During the review of any PMA, if a minor deficiency arises that requires the submission of a minor amendment, the 180 day clock will be stopped. Upon receipt of the amendment, the clock will be resumed but not reset, and the due date will be recalculated taking into account the hold period for the PMA.

D. PMAs with a Major Deficiency. If a major deficiency is found in a PMA that requires the submission of a major amendment, whether or not requested by ODE, the review clock will be suspended and the PMA will be put on hold. Upon receipt of the amendment, the 180 day review clock will be reset and, accordingly, a new due date established.

4. PMA Supplement Reviews.

A. PMA Supplements in General. Reviewers should be looking at their PMA supplement workload to see if there are supplements that can be completed without interfering with the review of supplements with an earlier due date. If found, such PMA supplements should be completed as soon as possible.

B. PMA Supplements with a Minor Deficiency. During the review of any PMA supplement, if a minor deficiency arises that requires the submission of a minor amendment, the 180 day clock will be stopped. Upon receipt of the amendment, the clock will be resumed, but not reset, and the due date will be recalculated taking into account the hold period for the supplement.

C. PMA Supplements with a Major Deficiency. On the other hand, if a major deficiency is found in a PMA supplement that requires the submission of major amendment, whether requested or not and with or without additional minor amendments, the review clock will be suspended and the supplement will be put on hold. Upon receipt of the amendment, the 180 day clock will be reset and, accordingly, a new due date is established.

Effective Date

This policy is effective immediately.

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More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)