MANAGING THE REVIEW OF SUBMISSIONS IN THE STARS QUEUE

I. PURPOSE

This document explains:

- how to review according to the Submission Tracking and Reporting System (STARS) queue, and

- that any exception to completing the review of submissions according to the queue will be infrequent and require prior written approval from the Center Director.

Management of the review of submissions should allow for (1) completion of the review of a sponsor's submission within the established target review date, (2) equitable processing of sponsors' submissions, and (3) efficient use of reviewers' time. The intent of this document is not to impede established review management practices that meet these goals. This document describes efficient review management practices as well as some unacceptable review management practices.

II. BACKGROUND

A. We receive many different types of submissions that are assigned individual target review dates based on statutory requirements (e.g., 180 days from date of receipt for original new animal drug applications (NADAs)), regulations, or CVM policy.[1] Through the STARS corporate database, reviewers have access to their

[1] The target review date is the date by which ONADE should take final action on a submission.

list of assigned pending submissions, i.e., their STARS queue of pending submissions (STARS queue). As a reviewer, you are expected to routinely work in order based on due dates that appear in their current STARS queue. The circumstances under which you may review a submission not in accordance with this document are infrequent.

III. HOW TO REVIEW ACCORDING TO THE QUEUE

The responsibility for "reviewing according to the queue" resides primarily with the individual reviewer, not at the Office, division, or even team level. Reviewers are responsible for managing their individual queue. Reviewers ensure that they allocate sufficient time for a thoughtful and thorough evaluation of each submission while completing other tasks assigned to them. The team leader and division director are responsible for the queue in the organizational unit and may reassign submissions to balance the workload or to ensure a timely review of a submission.

As a reviewer, you will generally complete the substantive review of a pending submission in the order the submission appears in their STARS queue, sorted by the assigned target review date. However, upon receipt of a newly assigned submission, you are to perform screening and administrative reviews unless other personnel have performed these tasks.

Appropriate personnel will screen all NADAs (i.e., original, supplemental, administrative, and abbreviated) within 30 days of receipt and all investigational new animal drug (INAD) submissions within 60 days of receipt to determine whether they are acceptable for filing or review.[2]

Either you or other designated personnel will perform the administrative review on all newly assigned submissions. The administrative review is completed as soon as you receive the submission and it involves determining whether any consultation(s) is necessary and making those consulting review requests. Prompt requests for consulting reviews are necessary in order to allow for sufficient time for the completion of these reviews.

[2] See P&P 1243.2050.

Often you won't be able to make further progress on or complete a review of a submission. For example, you may require additional information (e.g., a consulting review, a minor amendment or End Review Amendment (ERA) to the submission, or results of cGMP inspections is pending) to complete a review or need additional time to assure a thoughtful evaluation of a submission while continuing to work on other submissions. Until the additional information is received or you have had adequate time to assure a thoughtful evaluation, begin reviewing the next submission in the STARS queue. Depending on the time available, if it is inefficient to begin the review of a complex submission, use the time to complete the review of one or more relatively less complex submissions (e.g., drug shipment notices, food-use authorization requests, or minor changes and stability reports). However, review these less complex submissions according to their order in your STARS queue. Return to completing the review of the initial submission as soon as possible.

Note: In the case where you have requested an ERA, the target review date of the submission will change, potentially re-ordering the STARS queue. For more information on how the ERA affects the target review date, see P&Ps 1243.4070 (INAD protocol (E) submissions), 1243.4075 (INAD data (P) submissions), and 1243.5730 (NADAs).

"Q" submissions may be created for certain CVM-initiated actions related to one or more documents that are tracked in STARS. However, CVM staff should not create a "Q" submission as a result of a sponsor contact (e.g., e-mail, facsimile, or other media) that constitutes a request or provides information that should be officially submitted through DCU (in paper or electronic format).

"Q" submissions created for CVM-initiated actions related to a pending submission (e.g., to review the Freedom of Information Summary associated with the labeling and all other information minor technical sections) or an approved application (e.g., non-voluntary withdrawal of approval) should be assigned appropriate due dates and reviewed in the queue.

The review of submissions or applications in response to Congressional inquiries and Congressionally-funded initiatives (e.g., Brown amendment) related to STARS documents should also be tracked by creating a "Q" submission. These "Q" submissions should be assigned a due date intended to assure completion of the task within the mandated timeframe.

Meeting minutes prepared by CVM that relate to an assigned STARS submission may be completed earlier to ensure that the minutes are recorded accurately.

Bioresearch monitoring and pre-approval cGMP establishment inspection reports, including sponsor's responses to FDA's official inspection observations, are reports that are entered into the STARS database when received. You may review these reports along with the corresponding data submission, if one exists. Review these reports earlier if significant compliance action is contemplated (e.g., Warning Letters).

If submissions are related in such a way that reviewing them concurrently, even if they have different target review dates, will lead to a better or more complete scientific decision, consult with your team leader or division director first, then conduct the substantive review of the submissions together. Complete the review of related submissions by the earliest target review date.

Use good judgment in managing your queue. In order to maximize the timely review of submissions it is expected that an experienced reviewer will review multiple submissions concurrently. Get advice from your team leader or division director if questions arise regarding proper queue management.

Examples of unacceptable queue management include: 1) ignoring overdue submissions while completing on-time submissions, 2) repeatedly postponing the review of a difficult submission while completing other submissions, and 3) allowing a submission to go overdue, while completing a submission with a later target review date.

IV. PERMISSIBLE EXCPETION TO REVIEWING ACCORDING TO THE QUEUE

There may be an infrequent instance where a submission needs to be reviewed other than in accordance with this document. A manager may permit reviewing a submission other than in accordance with this document only with prior written approval from the Center Director.

V. REFERENCES

CVM Program Policy and Procedures Manual

1243.2050 – Refuse to file refuse to review

1243.4070 – Integrating an end-review amendment (ERA) into the investigational new animal drug protocol (E) submission review process

1243.4075 – Integrating an end-review amendment (ERA) into the investigational new animal drug data (P) submission review process

1243.5730 – Integrating an end-review amendment (ERA) into the new animal drug application process

V. VERSION HISTORY

December 3, 2002 – Original version

January 23, 2009 – Revised to include concepts related to the end-review amendment process and how end-review amendments impact queue order, remove information on expedited review, make minor editorial changes and update format.