MANAGING THE REVIEW OF SUBMISSIONS IN THE STARS QUEUE

I. PURPOSE

This guide describes the Office of New Animal Drug Evaluation's (ONADE) policy for managing the review of submissions in the Submission Tracking and Reporting System (STARS) queue. It explains:

- How to review according to the 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 guide is not to impede established review management practices that meet these goals. This guide describes efficient review management practices as well as some unacceptable review management practices.

II. BACKGROUND

ONADE receives many different types of submissions that are assigned individual target review dates[1] based on statutory requirements (e.g., 180 days from date of receipt for original new animal drug applications (NADAs)), regulations, or CVM policy (e.g., 50 days from date of receipt for a protocol containing no data that is submitted to an investigational new animal drug application (INAD file)).[2] Through the STARS

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

[2] ONADE may grant certain types of submissions expedited review status (ERS). For example, the CVM's Program and Procedures Manual Guide 1240.3135 provides the criteria under which CVM will expedite the

corporate database, reviewers have access to their list of assigned pending submissions, i.e., their STARS queue of pending submissions (STARS queue). Reviewers should routinely work in order based on due dates that appear in their current STARS queue. The circumstances under which a reviewer may review a submission not in accordance with this guide 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 should ensure that sufficient time is allocated 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.

Reviewers should 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.[3] However, upon receipt of a newly assigned submission, reviewers should perform screening and administrative reviews unless other personnel have performed the tasks.

Appropriate personnel should screen all new animal drug applications (i.e., original, supplemental, administrative, and abbreviated) within 30 days of receipt to determine whether they are acceptable for filing (21 CFR 514.110(c)). The appropriate personnel should perform a screening review of newly assigned submissions to determine whether a submission is acceptable for review within 60 days of receipt of INAD submissions.[4]

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review of new animal drugs that offer important advances in animal health. Guidance for Industry #121: Expedited Review for New Animal Drug Applications for Human Pathogen Reduction Claims provides the criteria under which CVM will expedite review of new animal drugs that make human pathogen reduction claims. ONADE assigns animal drugs that meet the criteria for ERS shorter review target dates. A reviewer should review a submission with a shorter review target date according to the STARS queue.

[3] Sponsors frequently contact CVM staff via email, facsimile or other media. If the contact constitutes a request or provides information that should have been officially submitted through DCU (in paper or electronic format), CVM staff should ask the sponsor to make a formal submission and should not create a "Q" submission. If sponsors are permitted to make submissions unofficially this will result in submissions inappropriately being reviewed outside of the STARS queue.

[4] See Guidance for Industry and Reviewers #119: How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug.

A reviewer or other designated personnel should perform the administrative review on all newly assigned submissions. The administrative review involves determining whether any consultation(s) are necessary and making the request for the consulting review(s) at the time the reviewer receives the newly assigned submission. Prompt requests for consulting reviews are necessary in order to allow for sufficient time for the completion of these reviews.

Often a reviewer cannot make further progress on or complete a review of a submission. For example, a reviewer may require additional information (e.g., a consulting review, information from a primary reviewer, a minor amendment to the submission requested by the reviewer, or results of CGMP inspections) to complete a review or may need additional time to assure a thoughtful evaluation of a submission while continuing to work on other submissions. Until additional information is received or the reviewer has had adequate time to assure a thoughtful evaluation, the reviewer may 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, a reviewer may use the time to complete the review of one or more relatively less complex submissions (e.g., drug shipment notices, slaughter authorization requests, or annual reports). However, a reviewer should also review these less complex submissions according to their order in the STARS queue. The reviewer should return to completing the review of the initial submission as soon as possible.

"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., a request to review NADA Day meeting minutes) 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) 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. A reviewer may review these reports along with the corresponding data submission, if one exists. Reviewers may 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, a reviewer may, after consultation with the Team Leader or Division Director, conduct the substantive review of the submissions together. The reviewer should complete the review of related submissions by the earliest target review date.

Reviewers should always use good judgment in managing their queue. In order to maximize the timely review of submissions it is expected that an experienced reviewer will review multiple submissions concurrently. However, a reviewer should also generally review these submissions according to their order in the queue or as described in this guide. If uncertainty exists, the reviewer should get advice from their Team Leader or Division Director.

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 EXCEPTION TO REVIEWING ACCORDING TO THE QUEUE

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