

**CENTER FOR VETERINARY MEDICINE
PROGRAM POLICY AND PROCEDURES MANUAL GUIDE 1243.3120**

**OFFICE OF NEW ANIMAL DRUG EVALUATION
REVIEWERS' CHAPTER**

EXPEDITED REVIEW PROCESSING

- I. Purpose
- II. Procedure for Request of Expedited Review Status for a Document
- III. Processing Expedited Review of Submissions
- IV. Withdrawal of Expedited Review Status
- V. Examples: Expedited Review Status Granted Letter, Expedited Review Status Denied Letter, and Expedited Review Status Withdrawal Letter

I. PURPOSE

CVM may grant Expedited Review Status (ERS) for applications for certain new animal drugs classified as important advances in animal health and for applications for new animal drugs intended to reduce human pathogens in animals. You should refer to the Center's guidance documents on Expedited Review for a discussion of how sponsors should make a request for ERS and the criteria CVM will follow for granting ERS.

This guide outlines the procedures reviewers should follow when processing a sponsor's request for ERS for an INAD or NADA.

The Expedited Review Processing guide offers:

- direction on the processing of requests for ERS status, and
- the review timeframes for the Center's evaluation of a sponsor's request for ERS.

II. PROCEDURE FOR REQUEST OF EXPEDITED REVIEW STATUS FOR A DOCUMENT

A sponsor may request Expedited Review Status for an INAD or NADA. The sponsor should provide pertinent information on the drug compound, the proposed indication, and the rationale for requesting ERS. The Center should consider ERS for the specific proposed indication for the new animal drug.

The appropriate primary division of the Office of New Animal Drug Evaluation (ONADE) should evaluate the request. The request for ERS review should be evaluated within 60 days. The ONADE reviewer should write a review of the request and a letter granting or denying the request for ERS.

A letter granting ERS should be signed by the ONADE Director. A letter denying the ERS should be signed by the primary Division Director. The primary reviewer should send courtesy copies of the letter granting ERS to appropriate consulting divisions in ONADE to inform them that ERS has been granted to an INAD or NADA. The Document Control Unit (HFV-199) issues the letter. If the ERS is the only action requested, the final action code to be entered into STARS is either:

- EXPEDITED STATUS GRANTED (040/033) or
- EXPEDITED STATUS DENIED (041/033)

If the ERS is not the only action requested, the non-final action code to be entered into STARS is either:

- EXPEDITED STATUS GRANTED (040) or
- EXPEDITED STATUS DENIED (041)

Unless a final action code is entered into STARS, the submission remains pending in the tracking system. The primary reviewer should also confirm that the STARS system has correct information on all RELATED DOCUMENTS relevant to an INAD or NADA that was granted ERS. This information is available on the Document Overview Report (on-screen or printed), and will be useful in making programming links between associated documents. **If the appropriate changes**

were not made, then the reviewer should contact Document Control Unit to make sure that the STARS tracking system is updated accordingly.

III. PROCESSING EXPEDITED REVIEW OF SUBMISSIONS

When a letter is issued granting ERS, the STARS tracking system should assign an adjusted review time to any subsequent (and pending) submissions. **When a consulting reviewer receives a courtesy copy of a letter granting ERS, they should consult their pending list in STARS for the revised due dates.** This means that any submission that is part of the INAD/NADA and is currently under review in the Center when ERS is granted should be assigned a new, shorter due date.

The date that ERS was granted is stored in the ERS DATE GRANTED field on the Document Overview Report. DCU Routing Slips for all subsequent submissions to the document will have an ERS flag to assist reviewers in identifying ERS submissions and managing their workload.

Shorter review times are used for submissions granted ERS. The review timeframes are adjusted based on a graded adaptation to the routine STARS timeframes, as described on the back of the STARS Movement form. The timeframes are:

Expedited Review Timeframes (days)

| Routine CVM Review Times | Adjusted CVM Review Times | Adjusted In-House Consulting Review Times |
|---------------------------------|----------------------------------|--|
| 50 | 45 | 36 |
| 100 | 60 | 48 |
| 180 | 90 | 72 |

All submissions to an INAD/NADA, whether granted ERS or not, will be evaluated and processed by the same process and standards; only the timeframe for applications granted ERS will be different.

IV. WITHDRAWAL OF EXPEDITED REVIEW STATUS

ERS for an INAD or NADA should be withdrawn if:

- information is available that refutes the initial classification, or
- there are other grounds as described in CVM guidances.

The primary reviewer should prepare a letter informing the sponsor that the ERS has been withdrawn and that the INAD or NADA will be evaluated in the routine timeframes.

The letter should state the reasons for the change in ERS and be signed by the Director of the Office of New Animal Drug Evaluation. The primary reviewer should send courtesy copies to appropriate divisions in ONADE to inform consulting reviewers of the status change. The primary reviewer should check the STARS tracking system to make sure that pending dates have been reset.

Subsequently, primary reviewers and consulting reviewers, upon receipt of the courtesy copy of the letter, should check their pending list in STARS for revised due dates.

At the time that a letter issues, an action code of EXPEDITED REVIEW STATUS WITHDRAWN (049) should be entered into the STARS database. This action resets the due dates for all pending and subsequent submissions to the routine timeframes. The Document Overview Report will reflect the change in status.

**V. EXAMPLES: EXPEDITED REVIEW STATUS GRANTED LETTER,
EXPEDITED REVIEW STATUS DENIED LETTER, AND
EXPEDITED REVIEW STATUS WITHDRAWN LETTER**

A Expedited Review Status Granted Letter:

INAD xxx-xxx, <submission code>

<Sponsor Name>

<Address>

Dear <Name>:

We refer to your investigational new animal drug application (INAD xxx-xxx) and your submission dated <date> requesting Expedited Review Status.

We have completed our review and find that your application meets the criteria for expedited review status. Your request is granted. <Insert a discussion of why the product is granted ERS.>

[If the sponsor's submission requested additional action as well as Expedited Review Status, a statement informing the firm of the total status of the submission should be included; for example, "Additional comments on your protocol will be forwarded in a separate letter."].

Future correspondence regarding this response should reference the correspondence date and our file number, INAD xxx-xxx, <submission code.>

If you need further information regarding this response, please contact <name> at <phone number.>

Sincerely yours,

<Signature block of Office Director>
Office of New Animal Drug Evaluation

Responsible Office: ONADE Quality Assurance Team (HFV-102).
Date: 11/16/2001

cc: HFV-199, INAD Orig. [Salmon]
HFV-110, HFV-130, HFV-105, etc. (Divisions and Staffs that may be affected
should be informed of the new status).

ec: electronic file information; refer to the SOP on electronic filing located at
R:/onade/_sop

<Author's name, HFV-#, date>

ERS GRANTED

B Expedited Review Status Denied Letter:

INAD xxx-xxx, <submission code>

<Sponsor Name>

<Address>

Dear <Name>:

We refer to your investigational new animal drug application (INAD xxx-xxx) and your submission dated <date> requesting Expedited Review Status.

We have completed our review and find that your application does not meet the criteria for expedited review status. Your request is denied. <Insert a discussion of why the product was denied ERS.>

Although we believe a careful and full review was made, you may wish to appeal the decision for denial. Information on the Center's appeal process can be found in CVM Policy and Procedures guide 1240.3130.

Future correspondence regarding this response should reference the correspondence date and our file number, INAD xxx-xxx, <submission code.>

If you need further information regarding this response, please contact <name> at <phone number.>

Sincerely yours,

<Signature block of Division Director>

Office of New Animal Drug Evaluation

cc: HFV-199, INAD Orig. [Salmon]

HFV-110, HFV-130, HFV-105, etc. (Divisions and Staffs that may be affected should be informed of the new status).

ec: electronic file information; refer to the SOP on electronic filing located at
R:/onade/_sop

<Author's name, HFV-#, date>

ERS DENIED

C Expedited Review Status Withdrawn Letter:

INAD xxx-xxx, <submission code>

<Sponsor Name>

<Address>

Dear <Name>:

We refer to your investigational new animal drug application (INAD xxx-xxx) for which expedited review status (ERS) was granted. <Insert a discussion of why the ERS status of the product is now being withdrawn.> The ERS originally granted to INAD xxx-xxx is withdrawn as of the date of this letter.

Although we believe a careful and full review was made, you may wish to appeal our decision. Information on the Center's appeal procedure can be found in CVM Policy and Procedures guide 1240.3130.

Future correspondence regarding this response should reference the correspondence date and our file number, INAD xxx-xxx, <submission code.>

If you need further information regarding this response, please contact <name> at <phone number.>

Sincerely yours,

<Signature block of Office Director>

Office of New Animal Drug Evaluation

cc: HFV-199, INAD Orig. [Salmon]
HFV-110, HFV-130, HFV-105, etc. (Divisions and Staffs that may be affected should be informed of the new status).

ec: electronic file information; refer to the SOP on electronic filing located at R:/onade/_sop

<Author's name, HFV-#, date>

ERS WITHDRAWN