
OFFICE OF NEW ANIMAL DRUG EVALUATION
REVIEWERS' CHAPTER

DOCUMENT ROUTING AND COPY DISTRIBUTION FOR BIORESEARCH MONITORING (BIMO) IN ONADE

I. PURPOSE

This Guide describes current procedures used for the following:

- Routing of an Establishment Inspection Report (EIR) in ONADE for review, and copy distribution for an EIR;

- Routing and distributing copies of a Request for a Bioresearch Monitoring Inspection (BIMO) Assignment, and a Request for a Status Check.

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

II. PROCEDURE

An Establishment Inspection Report (EIR) documents the findings and observations made by the District Office pursuant to the inspection of a facility or a study. An inspection package generally includes a form 481, Summary of Findings, and an FDA form 483, if needed. An EIR issued under the BIMO Program reports inspections of clinical or GLP studies. The BIMO inspection is usually conducted at the reviewer's request (see P&P Guide 1243.8220). The BIMO Control Number is assigned in the Center Bioresearch Monitoring and Administrative Action Team (BIMO Team), HFV-234, at the time an inspection is requested. HFV-234 assigns the final CVM classification, and issues a Classification Memo ("Close-Out" Memo) to the FDA District Office.

The EIR summarizes results of a BIMO inspection and usually provides one of the following possible recommendations from the FDA Field Office: No Action Indicated (NAI), Voluntary Action Indicated (VAI), or Official Action Indicated (OAI) classification under the BIMO program guides. EIRs are forwarded under a STARS Review Request and Movement Form (see ATTACHMENT). The reviewer receives the EIR through STARS as a specialty review request from the BIMO Team.

The ONADE Reviewer evaluates the EIR and determines whether the trial(s) may be used in support of a new animal drug application. The reviewer may either concur with the classification recommended by the District Office or may recommend another classification. (ONADE only evaluates and recommends classifications to Center BIMO Staff; it does not assign the final classification). The reviewer prepares an EIR review memorandum that includes the reviewer's classification recommendation.

The EIR and the EIR review memorandum with a recommendation for classification are returned to the BIMO Team.

The reviewer should use the STARS Review Request and Movement Form. The form should indicate routing through the Team and Division, if required by individual ONADE division policy, and then the package is sent back to the BIMO Team via HFV-103, Document Control Unit (DCU).

For distribution of copies of the EIR Review Memo, the reviewer includes a *cc: block* at the end of the review memorandum (Each destination is circled or checked to show the appropriate unit as designated in the cc: block). Refer to section III (**Distribution**).

III. DOCUMENT ROUTING AND COPY DISTRIBUTION FOR EIR REVIEW MEMORANDUM

Routing for an EIR Review Memo:

ONADE Team
ONADE Division Director
(Division Coordinator – Person assigned by Division Director to coordinate BIMO, if applicable)
HFV-103 (Document Control Unit)
HFV-234 (Center Bioresearch Monitoring And Administrative Action Team)

NOTE: The EIR Review Memorandum should be directed TO: HFV-234, CVM BIMO Team [The original is the signed copy of the EIR review (signed by reviewer, Team Leader, etc.), and will be filed in HFV-234].

Distribution copies for an EIR Review:

cc: HFV-199, INAD<xxx-xxx>
[BIMO Staff, HFV-234, forwards a copy to the DCU to be filed by HFV-199 in the original INAD, open volume].
HFV-XXX

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

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

BIMO EIR Review:

"BIMO EIR REVIEW" helps the DCU when filing in the INAD jacket. [Similar to "ACK," "APP," "INC," "AUTH," which are added as the short form of "Acknowledgment," "Approval," Incomplete," "Authorization," at the end of other types of action documents].

NOTES:
The ONADE reviewer makes copies and marks them for teams or divisions that want them, or provides copies to any unit for coordination. These copies should be placed in a separate folder, which will be sent with the EIR Review Memorandum to DCU by the BIMO Team (HFV-234). DCU will distribute any additional copies through the appropriate channels.

The HFV-199 copy is now filed in the INAD. In the past, the HFV-199 copy has also been filed in the NADA. We are shifting future BIMO related documents into the INAD. The reviewer should:

- provide the INAD Number associated with the NADA whenever submitting a Memorandum Request for Bioresearch Monitoring Assignment;

- designate an INAD copy (as above) in the cc: block when the EIR review memorandum is filed.

IV. DOCUMENT ROUTING AND COPY DISTRIBUTION FOR OTHER BIMO-RELATED DOCUMENTS

A. Memorandum Request for Bioresearch Monitoring Assignment:

The Memo Request for Bioresearch Monitoring Assignment is routed directly to or is hand-carried to HFV-234, (CVM BIMO Team). It is not routed through HFV-103 (DCU).

Routing for a Request for Bioresearch Monitoring Assignment:

ONADE Team Leader
ONADE Division Director (or Person assigned by Division Director to coordinate BIMO)
HFV-234 (CVM BIMO Team)

NOTE: The original Memorandum – Request for Bioresearch Monitoring Assignment – is directed TO: HFV-234, CVM BIMO Team. [This original is the signed copy of the Memorandum Request for Bioresearch Monitoring Assignment (signed by the ONADE reviewer, Team Leader, etc.), and is received and filed in HFV-234].

Distribution copies for a Memorandum Request for Bioresearch Monitoring Assignment:

cc: HFV-XXX, Team/Division Copy
[a copy is filed in Team/Division in appropriate INAD file or electronic file, according to Division policy for BIMO EIRs].
HFV-XXX

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

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

NOTE: There is no HFV-199 (DCU) copy of the Memorandum Request for Bioresearch Monitoring Assignment because the Assignment, when finalized and issued to the District Office, is distributed widely, with a copy sent to the INAD.

B. Memorandum Request for Status Check from CVM Bioresearch Monitoring Staff, HFV-234:

A reviewer may obtain a status check by sending the appropriate information including establishment information (name and location of laboratory or site inspected) to HFV-234. The informal memo requests the status of one or more Clinical Investigators, establishments (laboratories or sites inspected), or status of an NADA or INAD (as a part of the technical section review). It is used to obtain a Status Check memo to use in the Approval Package for an NADA approval.

The CVM BIMO Team responds with a memo stating the classification status of establishments and clinical investigators.

The procedure and timing of the request for status check is as follows:

A status check can be requested at two points in the application review process. First, prior to full review of the safety and effectiveness data, the reviewer can obtain a status check by providing information from the NADA, including the name of sponsor, the NADA number, related INAD number(s), a list of clinical investigators, and a list of non-clinical laboratories involved. If the BIMO status check indicates no problems with studies, a notation of memo source and date and the following statement are put in the first review:

> Bioresearch records in HFV-234 <*with reference to the clinical or GLP study*> were reviewed and do not provide an adequate basis for refusal to approve this application. Refer to memo dated <*date of HFV-234 status check."*>

Second, when the primary reviewer determines the NADA is approvable, they may then request a BIMO status check prior to preparing Folders A and B of the approval package. If the status check indicates no problems with studies conducted under the Bioresearch monitoring program, a notation is a made of the

BIMO Team memo and the following statement is put in the Memorandum Recommending Approval:

> Bioresearch records in HFV-234 <*with reference to the clinical or GLP study*> were reviewed and do not provide an adequate basis for refusal to approve this application. Refer to memo dated <*date of HFV-234 status check."*>

V. REFERENCES

FDA Compliance Program (CP) Guidance Manual: CP 7348.808, Good Laboratory Practice; CP 7348.810, Sponsor, Contract Research Organizations, and Monitors; CP 7348.811, Clinical Investigators

CVM Policy and Procedures Manual, Guide 1243.3200, Routing a Request to Obtain a Review for an INADA or NADA

CVM Policy and Procedures Manual, Guide 1243.8220; BIMO Inspection Request Process, June 10, 1994

Code of Federal Regulations 21 CFR 511.1

ATTACHMENT
STARS Review Request and Movement Form

I ###### M

Purpose of Submission	: 2001-### BIMO		**Expedited Status**	: N
Parent Submission	:		**Biennial Date**	:
Reference Submission	:			
Document Type	: INVESTIGATIONAL NEW ANIMAL DRUG			
Submission Type	: ESTABISHMENT INSPECTION REPORT		**Sub Classification**	:
Applicant	: DRUG SPONSOR			
Drug	: DRUG		**Primary Branch**	: HFV-234
CVM Archive Filename	:			
Correspondence Date	: 12/13/1996		**CVM Due Date**	: 08/10/1997
Received Date	: 06/26/1997		**Consulting Due Date**	: 09/06/2001
Reset Clock Date	:		**Meeting Date**	: 08/03/1997

Action Date	**Package ID/Description**	**Seq Number**	**From**	**To**	**Action Definition**
06/27/1997	ORIG, DUP, TRIP	1	HFV-199	HFV-234	TO PRIMARY

REVIEW REQUEST AND MOVEMENT FORM

Action Requested: ______________________________

For Reviewer Use:

Requested by: **Reviewer**______________________ **Telephone #:** ______________

________	HFV-	________	DATE:	/ /	INITIALS:	______
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