
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

REQUESTING A BIORESEARCH MONITORING (BIMO) STATUS CHECK

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I. PURPOSE

This document describes

- a Bioresearch Monitoring (BIMO) status check
- how and when to request a BIMO status check
- how to document the results of a BIMO status check.

II. WHAT IS A BIMO STATUS CHECK?

The BIMO compliance programs are used to inspect study facilities, clinical investigators, or sponsors/monitors/contract research organizations. The BIMO compliance programs help to assure the integrity of scientific testing and the reliability of test data submitted to FDA. At CVM, the BIMO program is overseen by the Office of Surveillance and Compliance's (OSC) Bioresearch Monitoring and Administrative Actions Team (BIMO Team).

A BIMO status check is a review by the BIMO Team of the inspectional history of the sponsors, contract research organizations, clinical investigators and the Good Laboratory Practices (GLP) laboratories involved in a specific (J)INAD or (A)NADA. The BIMO Team reviews the inspectional history and assesses any problems associated with the inspections or investigators (e.g., disqualified investigators). The BIMO Team also reviews inspection reports that were requested but not conducted, inspections

classified as Official Action Indicated (OAI), or other BIMO issues that could negatively impact a data review or a pending approval.

III. WHO IS RESPONSIBLE FOR REQUESTING A BIMO STATUS CHECK?

Target animal review groups in ONADE generally request BIMO status checks. Other review groups may request a BIMO status check for toxicology, residue, pharmacokinetic, and environmental submissions if needed to determine the inspectional history for their particular studies.

IV. WHEN TO REQUEST A BIMO STATUS CHECK

Typically, there are two times when you may request a BIMO status check from the BIMO Team– 1) if, prior to or during the course of a data review, you are trying to determine whether the inspectional history is adequate, and 2) to confirm that there is an adequate inspectional history when assembling the documentation for approval of a new animal drug application (NADA) or abbreviated new animal drug application (ANADA).

You may request a BIMO status check at any time during a data review. If you are requesting a BIMO status check for a pending (A)NADA, request the status check 1) immediately upon receipt of an administrative (A)NADA, or 2) for non-administrative (A)NADAs, no more than 60 days before the approval package is sent to the Quality Assurance Team.

V. HOW TO REQUEST A BIMO STATUS CHECK

If you want to request a BIMO status check, send an e-mail to the BIMO Team leader (HFV-234). Type “request for BIMO status check” in the subject line of the email. Provide the relevant information in the e-mail, including:

1. sponsor name,
2. drug (established name),
3. (A)NADA number, related (J)INAD number, and reference (A)NADA number, if applicable, and

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4. clinical investigator(s) and location(s); or non-clinical laboratory(ies) and location.

VI. HOW TO DOCUMENT THE RESULTS OF A BIMO STATUS CHECK

The BIMO Team usually responds to status check requests by email within five working days of the request. The response provides the inspectional history of the establishments and clinical investigators for the requested (A)NADA and/or (J)INAD, and a conclusion on the BIMO status.

A. Documenting status checks requested during a data review submission

If the BIMO status check indicates that there are no issues, document the status check results in your review.

If the BIMO status check indicates that there are issues, discuss with your team leader what action, if any, should be taken.

B. Documenting status checks requested for an approval package

If the BIMO status check indicates that there are no issues, document the status check results in the Memorandum Recommending Approval. Include the email from the BIMO Team in Folder B of the approval package.¹

If the BIMO status check indicates that there are issues, discuss with your team leader what action, if any, should be taken.

VII. REFERENCES

Code of Federal Regulations (Title 21)

Part 58 – Good Laboratory Practice for Nonclinical Studies

Part 511 – New Animal Drugs for Investigational Use

FDA Compliance Program Guidance (CPG) Manual

CP 7348.808 – Good Laboratory Practice

¹ See P&P 1243.3800 for specific procedures related to preparing an approval package.

CP 7348.810 – Sponsor, Contract Research Organizations, and Monitors

CP 7348.811 – Clinical Investigators

Program Policy and Procedure Manual 1243.3800 - Preparing and Processing an Approval Package

VIII. VERSION HISTORY

November 16, 2001 – original version

March 1, 2010 – The 1243.8220 document was reviewed by ONADE and Office of Surveillance and Compliance BIMO Team to determine if any changes needed to be made. The BIMO inspection request information was moved to a separate P&P. Edits were made to include more specific information, information for generic animal drug applications and investigational files, and reformat the document and make it conform to ONADE document principles.