PROCEDURES

OFFICE OF COMPLIANCE

PROCESS FOR THE TRANSFER OF OAI CASES FROM OSIS TO OSI

Table of Contents

PURPOSE

To provide direction to members of the Office of Scientific Investigations (OSI) and the Office of Study Integrity and Surveillance (OSIS) on the process when transferring Bioequivalence (BE) and Good Laboratory Practice (GLP) inspection cases with an interim Official Action Indicated (OAI) classification from OSIS to OSI. OSI and OSIS will follow this MAPP when transferring a BE or GLP inspection case with an interim OAI classification from OSIS to OSI.

BACKGROUND

OSIS, in CDER's Office of Translational Science (OTS), issues BE and GLP inspection assignments. Following inspections, OSIS receives the Establishment Inspection Report (EIR) and associated inspectional documents from FDA's Office of Regulatory Affairs (ORA). For potential OAI cases, the OSI Compliance Enforcement Branch (CEB), in CDER's Office of Compliance (OC), evaluates the inspectional findings.

RESPONSIBILITIES

Office of Study Integrity and Surveillance (OSIS) Project Manager (PM)

- Receives the EIRs and associated inspectional documents from ORA for BE and GLP cases and confirms that they are consistent with the assignment issued by OSIS.
- Provides the CEB Program Analyst (PA) with EIR and associated inspectional documents for cases with an interim OAI classification.

- Coordinates with OSIS Reviewer and CEB PA to schedule Significant Action Meetings (SAMs).

Compliance Enforcement Branch (CEB) Program Analyst (PA)

- Receives EIRs and associated inspectional documents for cases with interim OAI classifications from OSIS PM.
- Confirms case information has been entered into the Compliance Program Information System (Complies).
- Coordinates with the OSIS Reviewer and OSIS PM to schedule SAMs.

Office of Study Integrity and Surveillance (OSIS) Reviewer

- Notifies the OSIS PM when OSIS recommends that the ORA field classification be upgraded to OAI.
- Coordinates with the OSIS PM and CEB PA to schedule SAMs.

PROCEDURES

1. OSIS PM receives the EIRs and all associated inspectional documents for BE and GLP cases from ORA. The OSIS PM confirms the EIR and associated inspectional documents are consistent with the assignment issued by OSIS.
2. OSIS PM emails the CEB PA notification when an EIR is received from ORA with an ORA field classification of OAI, and when OSIS recommends that the ORA field classification be upgraded to OAI. The OSIS PM includes a link to the EIR and associated inspectional documents, in ORA Search and Retrieval (OSAR) and Enterprise Content Management Server/System (eCMS) in the notification email.
3. CEB PA receives EIRs and associated inspectional documents from the OSIS PM.
4. CEB PA confirms the case information has been entered Complies.
5. CEB PA coordinates with the OSIS PM and OSIS Reviewer to schedule a Significant Action Meeting (SAM).

RECORDS MANAGEMENT

The processes specified in this MAPP do not generate records owned by OC, according to the OC file plan and the procedure described in the *CDER Standard Operating Procedures for Incorporating Records Management into Processes*.

REFERENCES

1. 21 CFR 320, Bioavailability and Bioequivalence Regulations.
2. 21 CFR Part 58, Good Laboratory Practice For Non-Clinical Laboratory Studies.
3. Public Health Service Act, Section 505(i) and 520(g), as amended.

DEFINITIONS

Interim OAI classification –An indication that a particular case, either has an ORA field classification of OAI, or OSIS has recommended the ORA field classification be upgraded to OAI.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
12/20/2017	Initial	n/a
01/01/2020	1	Addition of Records Management section