
GENERAL REVIEW AND ENFORCEMENT POLICIES

REQUEST FOR CGMP ESTABLISHMENT INSPECTIONS

1. Purpose:

This guide describes the procedures for requesting establishment inspections to assure a firm has the capability to conduct operations as required by the appropriate cGMPs to fulfill the commitments listed in an NADA, ANADA, or DMF.

2. Procedure:

- a. Requests for inspections may be initiated to secure needed information regarding NADA/ANADA/DMF/VMF commitments related to cGMP requirements, special projects or compliance programs.
- b. All requests for inspections of domestic (U.S.) and foreign establishments are to be directed to the GMP Program Manager in HFV-140, ONADE, for issuance.
- c. Format of the Request:

A request for inspection of a U.S. or foreign establishment should contain the following information:

- (1) Designation as "Assignment Memo."
- (2) Firm name and address.

NOTE: In the case of a foreign establishment, the name of the U.S. agent should be provided.

- (3) NADA/ANADA/DMF/VMF number and related product.
- (4) Background and reasons for request. Information must be clearly and explicitly stated so that the investigator will know exactly the intent and scope of the request.

- (5) Information necessary to conduct the inspection properly.
- (6) Center contact officer familiar with the request in case the investigator needs clarification or has any questions. The contact person's name, phone number, and mailing symbol should be included.
- (7) Specific office to which the inspection report should be sent.
- (8) Estimate of time needed to complete assignments (hours).
- (9) Assignment priority (high or routine).
- (10) Data (product and PAC) codes.
- (11) Target completion date.

3. Responsibility:

Requests for pre-approval inspections are the responsibility of manufacturing reviewers in the Division of Manufacturing Technologies, ONADE.

The GMP Program Manager in HFV-140, ONADE, issues inspection assignments for U.S. domestic field activities requesting an assessment of the capability of a proposed establishment to operate in compliance with cGMP regulations. The Division of Manufacturing Technologies (HFV-140) GMP Program Manager also issues assignments for foreign inspections.

4. References:

ORA Field Management Directive No. 17 - Assignment Issuances to the Field-Guidelines for Headquarters Offices.

Compliance Program 7368.001 - Pre-Approval NADA and ANADA Inspections.

Compliance Policy Guide Manual, Chapters 7155a and 56c (MOUs).