
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

**ACCEPTABILITY OF SUBMISSIONS CONTAINING FOREIGN DATA TO SUPPORT
SAFETY AND EFFECTIVENESS**

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I. PURPOSE

This document provides the general criteria used to determine whether data developed in foreign countries are acceptable and are in the proper format for submission.

II. SUBMISSION OF DATA

Section 569B of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as modified by the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012, codifies FDA's longstanding practice of accepting foreign clinical data to support applications, provided the applicant demonstrates that the data are "adequate under applicable standards to support approval." All foreign data pertinent to evaluation of both safety and effectiveness must be submitted in the new animal drug application (NADA) as provided for in 21 CFR 514.1(b)(8)(iv) or submitted to the investigational new animal drug (INAD) file. This requirement also applies to abbreviated new animal drug applications (ANADA) and generic INAD files. Applicants are required to submit data from investigations or commercial marketing outside the United States, if it is available to them, regardless of whether it is favorable or unfavorable.

III. DETERMINING ACCEPTABILITY OF DATA FOR REVIEW

A. Is the data acceptable for filing

The reviewer assigned the submission or the designated person will check that all foreign data submitted are in their original form and in English and that all units are displayed in units used in the United States. If the data do not meet these criteria, you may choose to refuse to file or refuse to review the submission.¹

B. Evaluate foreign data used to support safety and effectiveness for the following criteria:

1. Non-clinical laboratory studies (safety): If we determine the foreign studies are satisfactory, they may be used to complete full NADA or ANADA requirements

¹ See P&P 1243.2050.

for non-clinical data for safety, and in the case of an ANADA, bioequivalence. Non-clinical laboratory studies submitted to support safety of a new animal drug must comply with good laboratory practice (GLP) regulations (21 CFR Part 58). Studies conducted under the Organization for Economic Co-operation and Development (OECD) GLP Guidelines (European GLPs) may be acceptable. There should be a statement accompanying the data that the study was conducted in compliance with GLP regulations, or if the study was not conducted in compliance with these regulations, a statement of the reason for noncompliance and its impact on the study. (See 21 CFR 514.1(b)(12)(iii)).

2. Effectiveness studies (conducted in the field): These studies must be conducted by personnel qualified by scientific training and experience to conduct such tests and include all the information required by 21 CFR 514.1(b)(8). Evaluate the data using the recommendations in the Good Clinical Practices guidance (CVM Guidance for Industry #85, VICH GL9).

3. Effectiveness studies (conducted in a laboratory): These studies may include dose confirmation studies or model studies submitted by the sponsor to support the effectiveness of a new animal drug. Although the GLP regulations in 21 CFR Part 58 do not apply to such studies, good clinical practices (GCP) principles are applicable to the conduct of these studies.

NOTE: Review any available inspection history in CVM's BIMO database for the foreign investigators and sites used in the study. If you cannot make a determination of validity, consider issuing an inspection request prior to accepting the data.²

C. Specific considerations regarding foreign effectiveness field studies

Because of differences in animal breeds, nutrition, husbandry practices, and disease, foreign field studies are not normally acceptable as fulfilling complete NADA requirements for effectiveness. They may, however, be used as at least a portion of the basis of approval, if the sponsor can show that the conditions of use are representative of the U.S. The sponsor should include a justification for using foreign sites.

NOTE: For anthelmintics and antimicrobials, susceptibility, strains, and husbandry practices will likely vary across geographic locations, which may impact the acceptability of the data. For more information on anthelmintics, see Guidance for Industry #90. For antimicrobials, the majority of data should be from U.S. sites. If the sponsor wants to use foreign clinical effectiveness trials for an antimicrobial product, they should provide evidence that the following are representative of the U.S.: pathogen susceptibility, antimicrobial susceptibility, and minimum inhibitory concentration (MIC) patterns.

IV. COMMUNICATING OUR FINDINGS WITH THE SPONSOR

Section 569B of the FD&C Act requires FDA to accept clinical data from foreign studies provided that those studies comply with applicable U.S. standards. There are many

² See P&P 1243.8220.

submission types that may contain foreign data. So, any determinations we make regarding the acceptability of the foreign data will be conveyed in the letter we issue in response to the submission received that contains that foreign data. It may be in the form of an acknowledgement letter, a technical section complete or incomplete letter or some other formal piece of correspondence. If there is a template for the correspondence, you will use that to template.

V. REFERENCES

Federal Food, Drug, and Cosmetic Act

Section 569B

Code of Federal Regulations (Title 21)

Part 58 – Good Laboratory Practice for Nonclinical Laboratory Studies

Part 514 – New Animal Drug Applications

§ 514.1, Applications

CVM Guidance for Industry

85 – Good Clinical Practices, VICH GL 9

90 – Effectiveness of Anthelmintics: General Recommendations, VICH GL7

CVM Program Policy and Procedures Manual

1243.2050 – Refuse to File and Refuse to Review

1243.8220 – BIMO Inspection Request Process

VI. VERSION HISTORY

January 26, 2009 –Original version of 1243.4068 prepared by the ONADE Policy and Procedures Maintenance Working Group. This original version replaces an older policy and procedure document titled 1240.3102 Use of foreign clinical and non-clinical data in an NADA.

May 9, 2018 – revised to include information about meeting our obligations under FDASIA and to be clear we will be communicating our findings regarding foreign studies submitted to support a technical section and approval. Also, reorganized some existing information in the P&P.