Contains Non-Binding Recommendations

136

Guidance for Industry

Protocols for the Conduct of Method Transfer Studies for Type C Medicated Feed Assay Methods

Final Guidance

Comments and suggestions regarding this guidance should be sent to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Comments may also be submitted electronically on the Internet at http://www.fda.gov/dockets/ecomments. All comments should be identified with the Docket No. 2006D-0441.

For questions regarding this guidance document, contact Rebecca L. Owen, Center for Veterinary Medicine (HFV-141), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240-276-9842, E-mail: rebecca.owen@fda.hhs.gov.

Additional copies of this guidance document may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at http://www.fda.gov/cvm.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
April 26, 2007

TABLE OF CONTENTS

Guidance for Industry[1]

Protocols for the Conduct of Method Transfer Studies for Type C Medicated Feed Assay Methods

Final Guidance

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

Section 512(b) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. §360b) establishes the requirements for a new animal drug approval. FDA regulations specify the information you (the sponsor) must submit as part of your new animal drug application (NADA) and the proper format for the NADA submission. 21 CFR §514.1. As part of your NADA submission, you must describe analytical procedures capable of determining the active component(s) of the new animal drug within a reasonable degree of accuracy and of assuring the identity of such components. 21 CFR §514.1(b)(5)(vii). This includes a description of practicable methods of analysis (assay methods) that have adequate sensitivity to determine the amount of the new animal drug in the final dosage form. 21 CFR §514.1(b)(5)(vii)(a). In the case of a Type A medicated article, the Type C medicated feed is a final dosage form used to treat the animal. Thus as part of the NADA review process, FDA looks at assay methods for determining the amount of a new animal drug in Type C medicated feed.

This guidance provides our (the Office of New Animal Drug Evaluation or ONADE) recommendations for protocols for conducting the transfer study of a single-laboratory validated Type C medicated feed assay method to laboratories that have no experience with the test method. Many testing laboratories, including state feed laboratories and contract laboratories, use Type C medicated feed assay methods to determine whether the drug in a medicated feed is within the assay limits. The term “assay limits” refers to the amount of the drug detected when a Type B/C feed is assayed. The limit is a range that is

[1] The Office of New Animal Drug Evaluation within the Food and Drug Administration’s Center for Veterinary Medicine prepared this guidance document.

published at 21 CFR §558.4(d). When feed assay values fall within this range, it indicates that the feed has been prepared with the correct amount of Type A medicated article. Because many different laboratories use medicated feed assays, it is important that the assay methods are reproducible. Sponsors should conduct method transfer studies to evaluate reproducibility. A method transfer study is part of the evaluation process for a Type C medicated feed assay method and demonstrates the transferability of the feed assay method among different laboratories by comparing the results each laboratory obtains when using the method to analyze a specific set of feed samples. Sponsors may expand the method transfer study to include other medicated feed products, such as Top Dress Type C, Free-Choice Type C, and Type B medicated feeds.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.

II. DISCUSSION

There are several steps involved in the development of a medicated feed assay method. First, you should write the feed assay method description and conduct a single-laboratory validation. The validation may be performed by a laboratory within your company or by an outside laboratory that you contract for this purpose. For additional information regarding the preparation and validation of a suitable medicated feed assay method, we recommend you consult the Center for Veterinary Medicine (CVM) guidance documents "Guidance for Industry #135: Validation of Analytical Procedures for Type C Medicated Feeds," and "Guidance for Industry #137: Analytical Method Description for Type C Medicated Feeds."

You should next evaluate the reproducibility of the feed assay method by conducting a method transfer study, where you compare results obtained by your reference laboratory[2] for fortified and medicated feed samples with results from participating laboratories[3] not familiar with the test method. Before beginning the method transfer study, you may wish to hold a method demonstration, where personnel from your reference laboratory demonstrate the assay method and you discuss the method and transfer study protocol with representatives from each of the participating laboratories. The transfer study itself should be conducted in two phases. The first phase is a method familiarization, during which the participating laboratories should assay control (unmedicated) and fortified feed samples to ensure that they understand the method and can perform the analysis. The second phase is the assay of the control, fortified, and medicated feed samples that

[2] The sponsor's own expert laboratory or a contract testing laboratory retained by the sponsor. The reference laboratory should have experience performing the assay method.

[3] Laboratory conducting the analytical phase of the transfer study. Usually there are three participating laboratories including contract testing laboratories and at least one state feed laboratory; however, federal government and foreign laboratories may also participate.

comprise the sample set for the transfer study. Each participating laboratory should provide a report documenting their data and results from the transfer study. The reference laboratory may also provide a separate report. The sponsor's study director should compile the results from the reference and participating laboratories to prepare a transfer study summary report. ONADE will use the report and data, along with the method description and single-laboratory validation, to evaluate the feed assay method.

This guidance includes recommendations to help you write a protocol for the transfer study of your validated feed assay method. You are not required to submit a method transfer study protocol to us for our review; however, our review and concurrence make it more likely that the study detailed in the protocol will generate information you can use to demonstrate that the assay method can be successfully implemented in laboratories with no previous experience performing the method. Therefore, we recommend that you submit the protocol to us, and that we agree on the format and content of the feed assay method transfer study before you begin the study. This document provides example protocol formats for the sponsor (App. I) and a participating laboratory (App. II). You may use these example protocol formats as they are presented, combine the example formats into one protocol for both the sponsor and the participating laboratories, or develop your own protocol format. Instructions for the reference laboratory are typically included in the sponsor protocol, but you may also choose to prepare a separate reference laboratory protocol. Your protocol(s) should include detailed instructions for all the procedures, operational steps, and documentation of the transfer study, including:

- identification of the participating laboratories and personnel;
- preparation of feed samples for analysis;
- analysis of the feed samples by your reference laboratory to provide the reference concentrations;
- method familiarization and analysis of the transfer study sample set by the participating laboratories, including the number and type of feed samples each laboratory will assay and the sample analysis sequence; and
- data reporting, data analysis techniques, and report formats.

We also recommend that you wait for us to conduct a technical evaluation of the Type C medicated feed assay method description and the single-laboratory validation report before you begin your method transfer study.

Selecting Participating Laboratories

We usually recommend that a sponsor conduct a three-laboratory transfer study for a new Type C medicated feed assay method associated with a new animal drug application for a new Type A medicated article. These laboratories should not be familiar with the test method. We recommend that at least one of the laboratories be a state feed laboratory. We usually recommend a one-laboratory transfer study for an updated or new feed assay method for an already approved Type A medicated article, and for Type A medicated articles intended for minor uses or minor species. If you perform a one-laboratory transfer study in a laboratory within your company, we strongly recommend that the laboratory not be involved in the development of the method.

Method Demonstration

We recommend that you hold a training session at which personnel from your reference laboratory demonstrate the method for representatives from the participating laboratories, to highlight or clarify practical details of the assay method. During the training session, you should also discuss all aspects of the protocol(s) to ensure everyone understands the procedures and objectives. This can help you identify key points that may cause difficulties in the transfer study, perhaps as a result of differences in laboratory procedures and equipment, or facility limitations. If the method demonstration shows the need for changes to the protocol(s) or method description, you should make the appropriate revisions before proceeding with the method transfer study. If you make changes, we recommend that you submit the revised method and protocol(s) to us for concurrence before you begin the laboratory phase of your method transfer study.

Feed Samples for the Transfer Study

We recommend that you prepare the medicated feeds used in the transfer study in at least pilot scale equipment using manufacturing processes comparable to the commercial manufacturing processes. We recommend at least a 1,000 pound batch size, and you should prepare at least two (2) batches of medicated feed, preferably in different mixer types. The drug concentration(s) in the medicated feed samples should be within a range of 0.5-1.5X the proposed label claim(s). You should include a description of the procedures for feed mixing, sampling, and homogeneity testing in the sponsor protocol. You should also state in the protocol that you will provide the specific feed formulas and batch records as appendices in your transfer study summary report.

You should prepare and distribute the test materials to the participating laboratories, including the analytical standards and control and medicated feeds that have been manufactured in typical feed mixing equipment. For each batch of feed you include in the transfer study, you should prepare five (5) feed samples, identified only by a sample identification number, that you will distribute to each of the participating laboratories. The sponsor usually grinds and sub-divides the medicated and control feeds before shipment to the participating laboratories; however, you may choose to include the feed grinding and sampling procedures in the transfer study. If a feed is already a fine or coarse powder, you may not need to grind this type of feed prior to sub-sampling. You should provide medicated feed samples of sufficient size to allow for at least duplicate analysis. For example, for an analysis that requires 150 grams of feed, each individual bag of medicated feed sample should contain over 300 grams of feed to allow for preparation of two (2) samples for analysis. You should also provide control feeds to the participating laboratories in single large samples sufficient to assay the method familiarization samples and the control and fortified samples included in the transfer study sample set. We recommend that you provide control feed sample amounts large enough to allow the participating laboratory to repeat the entire analysis at least three (3) times. You should specify in the sponsor protocol the number and weights of the sample bags that you will provide to each participating laboratory.

We recommend that you describe the shipment and storage of feed samples and the documentation procedures in both the sponsor and participating laboratory protocols. You should include expiration dates for the control and medicated feed samples, which should be consistent with the known storage stability of the drug in the feed. You should ship the samples at a time that will allow for the completion of the transfer study, in the absence of unreasonable delays, before the samples expire. If high moisture feed samples (e.g., a cattle finisher feed) are used, each participating laboratory should perform a loss on drying (LOD) test as close as possible to the time they prepare the feed samples for drug analysis, to determine the amount of moisture in the feed. You should monitor the moisture results to check for variability between samples due to shipping and/or storage. If you expect the participating laboratories to perform an LOD test, you should provide the LOD test method as an appendix to the sponsor and participating laboratory protocol(s). Your feed assay method description may include a calculation to adjust the concentration of the drug substance to a specific moisture level, if appropriate.

Determination of Reference Concentrations

Your reference laboratory should assay the same transfer study sample set you provide to the participating laboratories. The reference laboratory's analysis of the medicated feed samples determines the reference concentrations, to which you will compare the results obtained by the participating laboratories. If you retain a contract testing laboratory to determine the reference concentrations, you may prepare a separate reference laboratory protocol detailing this procedure and include it as an appendix to your sponsor protocol. You should provide the results of the reference laboratory analysis of the transfer study sample set to CVM at the initiation of the transfer study.

Transfer Study of the Assay Method

We recommend that the transfer study of the medicated feed assay method include two phases: a method familiarization, and the analysis of the transfer study sample set. In the method familiarization phase, participating laboratories assay control and fortified feed samples. This phase ensures that the participating laboratories understand the method and have the equipment and expertise to perform the analysis. You should provide instructions in the participating laboratory protocol to analyze a set of control and fortified feed samples and to evaluate the results against defined non-interference, recovery, and linearity criteria. Each participating laboratory should provide the method familiarization results to the sponsor's study director and wait for sponsor agreement before proceeding with the transfer study. We strongly urge you to include a method familiarization step in your transfer study protocol, particularly if you do not hold a method demonstration for the participating laboratories.

The participating laboratories may suggest modifications to the feed assay method before they begin the transfer study. The participating laboratory protocol should describe the process by which a participating laboratory should propose any feed assay method modifications to the sponsor's study director. The sponsor's study director should approve any modifications to the feed assay method before the participating laboratory conducts the transfer study.

The second phase of the transfer study is the analysis of the transfer study sample set. The reference laboratory and participating laboratories should each assay the following samples:

- Five (5) replicates of control feed samples.
- Five (5) replicates of control feed samples fortified at 0.5X the lowest label claim.
- Five (5) replicates of control feed samples fortified at 1X the label claim (if a range of concentrations is being transferred, fortify control feeds at both 100% of the lowest concentration level and 100% of the highest concentration level).
- Five (5) replicates of control feed samples fortified at 1.5X the highest label claim.
- Five (5) replicate samples of each batch of medicated feed. You should prepare at least two (2) batches of medicated feed, and you should provide five (5) individual portions of each batch; thus, each participating laboratory receives at least ten (10) blinded medicated feed samples.

The sponsor protocol should describe the samples included in the transfer study sample set. The participating laboratory protocol should include all information the participating laboratory needs to assay the transfer study sample set. You should state the transfer characteristics that the participating laboratory will investigate and how these characteristics are to be investigated (e.g., the number of analyses the participating laboratory will conduct, the number of replicates of individual standards they will use to prepare standard curves, etc.). You should provide the criteria for acceptability of the data, as well as the criteria for re-analysis. The protocol should state that the participating laboratory should explain any re-analysis it performs with a scientifically supportable justification.

We recommend you instruct the participating laboratories to analyze the transfer study sample set over several days, in sub-sets that include all of the sample types, to demonstrate that the method will provide the same results on different days. You may wish to provide the participating laboratories with a specific sample analysis sequence, to ensure that they assay each sample type over multiple days. In addition, specified sample sets allow for easier auditing and data analysis.

Reports

The participating laboratories and the sponsor's study director should prepare reports. The reference laboratory may also prepare a report.

Each participating laboratory should prepare a report documenting its results for the method transfer study. The participating laboratory protocol should specify the items that the participating laboratory should include in the report. The following are some examples of items you may want to ask the participating laboratory to provide:

- A summary of the method familiarization results (without copies of the chromatograms and raw data).
- Individual and summary results for the transfer study sample set in tabular form.
- A discussion of the laboratory study and a description of any difficulties or problems and their resolution.
- A description of any deviations from the test method and recommendations for clarifying operational steps that were not clearly described in the method.
- Signatures of the individuals responsible for the conduct of the transfer study.

The participating laboratory protocol should also provide a format for the report. You may wish to provide the following types of instructions and forms in the protocol, to ensure results from each laboratory are reported in an appropriate format:

- Instructions for rounding the numerical results.
- Templates for reporting analytical data in a standard format.
- Instructions to append copies of all the chromatograms for the transfer study sample set, system suitability test results, and standard curves.

If you retain a contract testing laboratory as your reference laboratory, that laboratory should prepare a report documenting its results for determination of the reference concentrations. You should provide the reference laboratory report as an appendix to your study director's transfer study summary report (described below). If the reference laboratory is your own expert laboratory, you may choose to provide the reference laboratory results as a section of the study director's transfer study summary report, rather than preparing a separate report. You should document in the sponsor protocol and/or reference laboratory protocol how you will report the reference laboratory results. You should present the raw data and results for the reference laboratory analysis of the transfer study sample set using the same forms and format as the participating laboratories.

The sponsor’s study director should prepare a transfer study summary report. Normally, this report includes a comparison of the reference and participating laboratory results for the transfer study sample set and a discussion of the participating laboratory reports, specifically addressing any problems or comments from the participants. The sponsor protocol should describe the structure of the summary report and specify the items that you will include in the report. The following list provides examples of items you may want to include in your summary report:

- Copies of the reference and participating laboratory reports, including copies of the chromatograms for the transfer study sample set.
- The key to the blinded medicated feed samples.
- A tabular summary of the individual and average results the participating and reference laboratories reported for the transfer study sample set.
- A discussion and comparison of the results and observations included in the reference and participating laboratory reports.

- An assessment of the transfer study results and documentation of any issues or changes made to the results based on the data audit.
- A copy of the feed assay method that ONADE evaluated.
- If appropriate, a summary of proposed changes to the feed assay method and the revised method description.
- Copies of the signed protocol(s). Note: If you have a single transfer study protocol that covers both the sponsor and the participating laboratories, the protocol should include signature blocks for both the sponsor and participating laboratories personnel.
- Signatures of the individuals responsible for the conduct of the transfer study.

ONADE's evaluation of the method description, the single-laboratory method validation, and the results from the method transfer study will be the basis for acceptance of the feed assay method.

The Table on the following page illustrates the flow of activities we recommend for conduct of the transfer study.

Table

Recommended Flow of Activities

PHASE OF THE TRANSFER STUDY	ACTIVITY	PARTICIPANTS
Method Description & Single-Laboratory Method Validation & Transfer Protocol	Medicated feed assay description and single-laboratory validation	Sponsor
	Technical review	ONADE
	Modification of feed assay and/or additional supporting data	Sponsor based on ONADE comments
	Technical review	ONADE
	Method transfer study protocol(s)	Sponsor
	Protocol(s) review and concurrence	ONADE
Laboratory	Method demonstration (optional)	Sponsor, ONADE, Reference Laboratory, Participating Laboratories
	Submission of any revisions to the protocol for review and concurrence (optional)	Sponsor, ONADE
	Preparation and distribution of the control and medicated feed samples	Sponsor
	Determination of the reference concentrations	Reference Laboratory
	Method familiarization	Participating Laboratories with Sponsor oversight
	Analysis of the transfer study sample set	Participating Laboratories
Reporting	Data audit and preparation of the study report	Participating Laboratories
	Analysis of the participating laboratory reports, data audit, method revision and preparation of the reference laboratory and sponsor study director's transfer study summary reports	Sponsor, Reference Laboratory
	Submission of summary report to ONADE	Sponsor
Evaluation of the Type C Medicated Feed Assay Method	Method and data evaluation	ONADE

Appendix I

Example Sponsor Protocol

1. Objective

This section should clearly state the objective of the study and identify the drug and animal species and number of participating laboratories.

2. Scope

This section should state that the transfer study is designed to evaluate an official method of analysis for a drug for use at specified concentrations in the preparation of medicated animal feeds for specific species.

3. Quality Audit

We recommend that a qualified person not involved with the transfer study perform a 100% data audit of the reference and participating laboratory reports. The quality audit section of the protocol should state that this will occur and should also include specific information, such as the name of the person performing the audit and his or her affiliation.

4. Responsibilities

This section should list the sponsor personnel conducting the transfer study and evaluating the results and it should identify their responsibilities. You should include contact information. The following chart provides examples of the personnel you should include in this section:

Sponsor's Study Director:	Name Affiliation Address and Contact Information Description of Responsibilities
Investigators:	For each investigator: Name Affiliation Address and Contact Information Description of Responsibilities

ONADE Representative[4]:	Name Affiliation Address and Contact Information Description of Responsibilities

5. Definitions

This section should provide definitions for terms used in the protocol. As much as possible, you should use terms consistently in the sponsor and participating laboratory protocols. The following chart provides examples of definitions you may wish to include in this section:

Reference Laboratory:	The sponsor's own expert laboratory, or a contract testing laboratory retained by the sponsor that has experience performing the assay method.
Reference Concentration:	The concentration of the drug substance in the medicated feed samples as determined by the reference laboratory.
Participating Laboratory:	Laboratory conducting the analytical phase of the transfer study.
Investigators:	The scientists who will prepare the samples for distribution to the participating laboratories and/or analyze the feed samples using the proposed feed assay method.
ONADE Representative:	The person designated by ONADE to review the protocol(s) and summary report, oversee the project, and provide guidance on issues as they may arise during conduct of the study.

6. Assay Method

This section should identify the feed assay method you propose. You should include the feed assay method as an appendix.

7. Reagents & Chemicals

This section should identify any specific equipment, reagents or chemicals, such as analytical standards, you will supply to the participating laboratories. This section of the protocol should state that you will provide appropriate information, such as Certificate of Analyses, lot numbers, expiration dates, and material safety data sheets.

[4] ONADE assigns this representative. You should contact ONADE to determine the representative for your method transfer study and include the representative's contact information in your protocol(s).

8. Feed Preparation, Determination of Reference Concentrations, Storage and Shipment

This section should describe the procedures you will use to prepare the control and medicated feed samples, and to determine and document the reference concentrations for the medicated feeds. You should also describe the preparation and shipment of the control and medicated feeds to the various laboratories involved in the transfer study. You should include how the participating laboratories will document receipt of the feed samples, and provide appropriate storage conditions and expiration dates.

9. Transfer Study Sample Set

This section should describe the number and types of samples the reference and participating laboratories will assay during the transfer study.

10. Conduct of the Feed Assay Transfer Study

This section should reference the participating laboratory protocol for a description of the analysis of the samples and should include a list of the names, addresses, telephone and fax numbers, and other relevant information for the participating laboratory personnel involved in the transfer study. You may specify time frames for the conduct of the transfer study and for reporting the data from the study.

This section should also define the kind of written and verbal communication you expect to occur between the sponsor study director and the participating laboratory personnel, as well as procedures for documenting such communication.

11. Amendments to or Deviations from the Protocol

This section should describe the process by which the sponsor may amend the protocol(s) and the mechanism for recording deviations from the protocol(s), and identify the individuals responsible for approving such amendments or deviations. This section should also specify the mechanism by which the participating laboratories may propose changes to the feed assay method and report any deviations or problems encountered in the conduct of the feed assay method.

12. Reference Laboratory and/or Summary Report(s)

This section should describe the structure of the reports the sponsor and the reference laboratory will prepare and specify the items that you will include in your transfer study summary report.

Appendix II

Participating Laboratory Protocol

1. Objective

This section should clearly state the objective of the study and identify the drug and animal species.

2. Scope

This section should state that the transfer study is designed to evaluate an official method of analysis for a drug for use at specified concentrations in the preparation of medicated animal feeds for specific species.

3. Quality Audit

We recommend that a qualified person not involved with the transfer study perform a 100% data audit of the participating laboratory report. The quality audit section of the protocol should state that this will occur and should also include specific information, such as the name of the person performing the audit and his or her affiliation.

4. Responsibilities

This section should list the participating laboratory personnel conducting the transfer study and evaluating the results and their responsibilities. You should include complete contact information. The following chart provides examples of the personnel you should include in this section:

Participating Laboratory Study Coordinator:	Name Affiliation Address and Contact Information Description of Responsibilities
Investigators:	For each investigator: Name Affiliation Address and Contact Information Description of Responsibilities
ONADE Representative[5]:	Name Affiliation Address and Contact Information Description of Responsibilities

[5] ONADE assigns this representative. You should contact ONADE to determine the representative for your method transfer study and include the representative's contact information in your protocol(s).

5. Definitions

This section should provide definitions for terms used in the protocol. As much as possible, you should use terms consistently in the sponsor and participating laboratory protocols. The following chart provides examples of definitions you may wish to include in this section:

Participating Laboratory:	Laboratory conducting the analytical phase of the transfer study.
Investigators:	The scientists at the participating laboratory who will analyze the feed samples using the proposed feed assay method.
ONADE Representative:	The person designated by ONADE to review the protocol(s) and summary report, oversee the project, and provide guidance on issues as they may arise during conduct of the study.

6. Assay Method

This section should identify the feed assay method you propose. You should include the feed assay method as an appendix.

7. Reagents & Chemicals

This section should identify the specific equipment, reagents and chemicals the participating laboratory will use in the laboratory phase of the study, such as analytical standards, HPLC system, and analytical reagents. This section should also identify which of these materials you will supply to the participating laboratory.

8. Transfer Study Feed Samples

This section should include information for documentation of sample arrival and use at the participating laboratory, storage conditions and expiration dates for the samples, and instructions for disposal of materials at the end of the study. You should reference and append any documentation forms. This section should also state that the participating laboratory will not assay any feed samples outside the expiration dating periods.

9. Laboratory Transfer of the Medicated Feed Assay Method

This section provides instructions for the method familiarization and the analysis of the transfer study sample set. The information in Section 9 of the sponsor protocol describing the transfer study sample set should be repeated here.

This section should include the time frames for the participating laboratories to conduct and report the interim and final data to the sponsor. If appropriate, this section should state how and where the participating laboratories will archive the raw data.

This section should also define the kind of written and verbal communication you expect to occur between the sponsor study director and the participating laboratory personnel, as well as procedures for documenting such communication.

10. Amendments to or Deviations from the Protocol

This section should describe the process by which the sponsor may amend the protocol(s) and the mechanism for recording deviations from the protocol(s), and identify the individuals responsible for approving such amendments or deviations. This section should also specify the mechanism by which the participating laboratories may propose changes to the feed assay method and report any deviations or problems encountered in the conduct of the feed assay method.

11. Participating Laboratory Report

This section should provide a format for the participating laboratory report and specify the items that the participating laboratory should include in the report.