
GENERAL REVIEW AND ENFORCEMENT POLICIES

CRITERIA FOR VETERINARY MEDICAL REVIEW OF
ESTABLISHMENT INSPECTION REPORTS

I. Purpose:

This document provides information to assist in the review of the veterinary medical aspects of the Establishment Inspection Reports (EIRs).

II. General:

In reviewing establishment inspection reports, the veterinary medical officer should attempt to be fully responsive to the questions contained in the covering referral memorandum. The questions directed to the Veterinary Medical Officer should be well considered, pertinent, and as specific as possible. The answers should be written as detailed as is necessary to reply fully to the inquiry. The review should relate primarily to medical matters and may extend into interpretation of the law of regulations as requested. Comments will be forwarded to the Team originating the inquiry.

III. Review Responsibility:

Primary responsibility for veterinary medical review of establishment inspection reports is as follows:

- A. Division of Surveillance personnel shall review cases involving labeling, adverse drug events, and injury reports.
- B. Division of Animal Feeds personnel shall review cases involving violative tissue residues resulting from medicated feeds. Division of Human Food Safety personnel shall review all tissue residue cases.
- C. Office of New Animal Drug Evaluation personnel shall review EIRs resulting from inspections under the three bioresearch monitoring compliance programs:

CP7348.808 - Good Laboratory Practice (nonclinical labs.). check CP's

CP7348.810 - Sponsors, CRO's monitors.

CP7348.811 - Clinical investigators.

IV. Veterinary Medical Aspects of the EIR:

A. Labeling:

The following general criteria should be considered when reviewing EIRs for labeling violations:

1. Is the product a drug, device, food, or additive?
2. Brand name and generic name,
3. Formulation--qualitative and quantitative,
4. Dosage directions,
5. Accuracy of claims,
6. Species,
7. Efficacy of ingredients for therapeutic claims,
8. Warnings or cautions,
9. Prescription or over-the-counter status, and
10. Regulatory status.

In all reviews the Veterinary Medical Officer should state, where possible, the manner in which label or formulation changes would bring the product into compliance.

B. Injury Reports:

In reviewing injury reports, the Veterinary Medical Officer should consider:

1. An interview with the attending veterinarian and owner, or in the alternative, to request the Division of Compliance to issue an assignment to obtain this information.
2. The possibility that the injury could be a direct result of the proper use of the product, misuse of the product, or to other factors.

3. No final decision should be formulated until all pertinent facts are available for review.
4. All adverse drug events; industry injury reports involving drugs or devices should be referred to HFV-210 in order to properly evaluate and to incorporate these reports into the marketed product experience reporting system.

C. Drug Carry-Over, or Good Manufacturing Practices Deviations:

Where there is potential for drug carry-over or GMP violations are reported in manufacture of products for food animal use, the medical review should relate to the potential for drug residues in the target animal's edible tissues and the necessity for a human health hazard evaluation. Failure to adhere to GMP requirements such as lack of sterility testing should be evaluated in the light of the potential health hazard to the animal and/or to humans where food-producing animals are involved.

D. Impact of deviations in compliance with 21 CFR 58 and 511 on the acceptability of data audited during inspection:

The preclearance reviewer should refer to the Reviewer's Training Manual Chapter on Bioresearch Monitoring which contains guidance for the information which should be included in the review. This guidance is contained in Attachments C, D, and E of this chapter.