GENERAL REVIEW AND ENFORCEMENT POLICIES

TYPES OF ENFORCEMENT ACTIVITIES

1. Purpose:

This guide describes the types of activities, considerations and evaluations involved in administrative and regulatory actions which assure compliance with the Federal Food, Drug, and Cosmetic Act as it applies to veterinary products and animal feeds.

2. Types of Enforcement Activities:

a. Enforcement activities and actions which result in correction of existing violations, prevention of future violations, removal of violative goods from the market, or punishment of offenders may be categorized as:

(1) Administrative actions such as withdrawal of approval of new animal drug applications, terminating investigational new animal drug exemption, withdrawal of eligibility to receive investigational new animal drugs, debarment actions, withholding approvals of new animal drug applications, abbreviated new animal drug applications, medicated feed applications, and food additive petitions.

(2) Regulatory actions such as seizure, prosecutions, and/or injunctions.

(3) Warning letters.

(4) Recalls. Recalls are voluntary actions by the industry.

b. Criminal prosecution actions may be recommended in those cases where, (1) there are clear and substantial violations, (2) there is evidence strong enough to warrant the belief that after a fair trial the defendants would be found guilty beyond a reasonable doubt, and (3) it is reasonable and just to put the defendants through the rigors of the criminal process. Except in cases involving a health hazard, fraud, or gross violations, prior warning is ordinarily given under current FDA policy to the firm or individual(s)

involved. Under Section 305 of the FD&C Act the person against whom criminal proceedings are contemplated must be given notice and an opportunity to present his views either orally or in writing, before a criminal referral is made to the U.S. attorney. Certain exceptions and procedural regulations are contained in 21 CFR 7.84 -7.87.

c. Seizures are civil actions against goods, the intent being to remove violative goods from the marketplace.

d. Injunctions are civil actions against firms and individuals designed to stop or prevent the occurrence of violations, and to require compliance with applicable laws and regulations. Temporary restraining orders may be included.

e. Warning letters are addressed to responsible individuals advising them of violations requiring correction and constitute one form of prior warning under current Agency policy.

f. Voluntary corrective actions often preclude the necessity for enforcement actions.

g. Refusals to approve applications, withdrawal of approvals and revocation of investigational exemptions are administration procedures intended to insure the safety and effectiveness of veterinary products.

3. Authority:

Federal Food, Drug, and Cosmetic Act:

a. Section 301 specifies the prohibited acts.

b. Section 302 provides authority to enjoin firms and individuals through court action.

c. Section 303 establishes the penalties for violating provisions of Section 301.

d. Section 304 provides for seizure of violative products through court action.

e. Section 305 provides for a notice and opportunity to present one's views before criminal prosecution is instituted.

f. Section 306 provides for written notice of minor violations in lieu of seizure, prosecution, or injunction proceedings.

4. Criteria for Enforcement Action:

Statutory Criteria. There are certain statutory bases for taking action against marketed drugs, animal foods and feeds, and veterinary medical devices. These include:

(a) Product labeling which is false or misleading in any particular.

(b) A product which is adulterated in any manner. The adulteration may or may not cause it to be a danger to health, but regardless or the danger, adulteration per se is a violation of the law.

(c) A product which is a danger to human or animal health.

(d) A product which is an economic fraud.

(e) A product which is misbranded for reasons other than those already mentioned.

(f) A product which is a new animal drug without an approved new animal drug application or exemption for investigational use.

(g) A product which is or contains a food additive without a food additive regulation.

5. Additional Information:

For more specific details regarding enforcement actions, Warning Letters, and recalls, refer to Regulatory Procedures Manual. For administrative actions refer to 21 CFR, particularly Parts 12, 511, 514, and 571.