DRUG EXPERIENCE REPORTING BY VETERINARIANS

Extensive pretesting by the manufacturer and careful review by FDA prior to approval does not preclude detection of long-term effects, effects in special subpopulations, drug-disease interactions, or conditions of use which may result in adverse reactions, once the drug is on the market.

The voluntary assistance of members of the veterinary medical profession has been enlisted to report adverse effects, increase in frequency, injury, unexpected side effects, sensitivity, lack of efficacy, and other adverse reactions.

I. Purpose:

This document describes the operation of the drug reporting system established for use by the veterinary medical profession.

II. Reporting System for Use by the Veterinary Medical Profession:

A. FDA has developed a system to encourage practicing veterinarians to report adverse reactions of drugs. The reports are submitted on Form FDA 1932a, "Veterinary Adverse Reaction, Lack of Effectiveness or Product Defect Report." This is a pre-addressed, franked postcard which is filled out and dropped in the mail by the veterinarian.

B. FDA distributes Form FDA 1932a to veterinarians through:

1. State/National veterinary medical associations/conferences;

2. FDA District Offices; and

3. Direct requests from veterinarians;

4. FDA/CVM Website - http://www.fda.gov/cvm/adereporting.htm

C. In some instances, CVM may require more detailed information about the incident and the practitioner will be called by a veterinarian. In any event, all FDA 1932a Forms are acknowledged by letter and another FDA 1932a are sent to the veterinarian for future use.

D. Suspected adverse drug experiences may also be reported by calling toll free 1-888-FDA-VETS. Calls will be forwarded to CVM's Division of Surveillance. The number is also equipped with voice-mail to receive messages and the calls will be returned by a veterinarian of the Division.

E. Whenever the opportunity presents itself, all individuals in CVM should encourage practitioners to report adverse drug effects to CVM.

Responsible Office: Division of Surveillance, HFV-214
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