DRUG EXPERIENCE REPORTING REQUIREMENTS

Applicants holding approved new animal drug applications are responsible for establishing and maintaining records concerning experience with the drug and Type A Medicated Articles containing the drug and for making reports of those experiences (21 CFR 514.80) to the Division of Surveillance. These reports are known as Drug Experience Reports (DER).

I. Purpose:

This document summarizes the drug experience reporting requirements of applicants holding approved ANADAs/NADAs.

II. Drug Experience Reporting Requirements:

The following summarizes the requirements in 21 CFR 514.80:

A. The regulations require that applicants, including distributors, holding approved ANADAs/NADAs establish and maintain records and make reports of:

1. Unpublished reports of clinical or other animal experience, studies, investigations or tests conducted or reported to the applicant;

2. Experience, investigations or studies involving the physical or chemical properties of the animal drug;

3. Copies of labeling that accompany the drug and copies of promotional labeling;

4. Advertising for drugs that are labeled for use by or on the order of a licensed veterinarian;

5. Quantities of the drug distributed to facilitate assessment of adverse effects;

6. Summary of reports of increased frequency of adverse drug experience;

7. Mix-ups with the new animal drug or its labeling;

8. Changes or deterioration of the new animal drug or failure of a batch to meet specifications;

9. Unexpected side-effects, injury, toxicity, sensitivity reaction, or unexpected incidence or severity of side-effects associated with chemical use irrespective of attribution to the new animal drug;

10. Failure of new animal drug to exhibit expected pharmacological action.

B. Reports shall be submitted to the Division of Surveillance at intervals of 6 months for the first two years following approval and annually thereafter on items 1-5 above.

C. Reports shall be submitted to the Division of Surveillance immediately on items 7 and 8 above.

D. Reports shall be submitted to the Division of Surveillance within 15 working days on items 8, 9 and 10 above.

E. Promotional labeling shall be submitted at the time of initial dissemination and advertisements for prescription drugs at the time of initial publication. However, to avoid unnecessary duplication in reporting, the distributors may send their annual reporting information to the NADA/ANADA holders who in turn shall compile such information into **one** report and submit to the Division of Surveillance.

III. Anniversary Date for Filing Drug Experience Reports:

A. The date of the initial new animal drug application approval will constitute the anniversary date for all drug experience reports, except as noted in paragraph III.B.

B. Complete drug experience reports will be filed for each approved new animal drug application. Two or more approved new animal drug applications having the same active ingredient may be combined under one report that includes all the information common to the group and all specific information, including marketing data and labeling separately for each approved ANADAs/NADAs covered (21 CFR 514.80(c)). The anniversary date assigned to the group will be that of the first individual new animal drug application approved.

C. The 6 month reports must be submitted within 30 days following the end of 6 month reporting period. The yearly periodic reports must be submitted within 60 days of the anniversary date of approval of the ANADA/NADA.