REVIEW AND EVALUATION OF DRUG EXPERIENCE REPORTS

I. Purpose:

This document establishes criteria and responsibilities for the consolidation, screening, review, and evaluation of drug experience reports required under 21 CFR 514.80 and adverse reaction reports from all sources.

II. General:

A. The review and evaluation of all drug experience reports are concerned with:

1. The overall marketing status of the drug.

2. Possible violations ranging from those affecting one or more batches of a drug by one manufacturer to those affecting a class of drugs or the production of several firms.

B. The objective of the review and evaluation is to provide an unbiased basis for the following types of decisions:

1. No change in the status of the drug.

2. Continued marketing requires changes in labeling, manufacturing procedures, and/or the generation of additional data.

3. Removal from the market.

III. Responsibilities for Review, Abstract or Summary:

A. The Division of Surveillance is responsible for consolidation of all drug experience reports, necessary referrals and consultations, and preparation of a summary report or abstract constituting the Center evaluation.

B. The Division of Surveillance is responsible for initiating regulatory procedures necessary for compliance.

IV. Criteria for Review and Evaluation of Adverse Drug Reactions:

Basic considerations to be used in all adverse experience reports are:

A. Value or uniqueness of drug--however, this only applies in the action sequence--not in review of the report itself.

B. Seriousness and nature of the problem.

C. Whether drug is a new animal drug covered by an approved NADA or ANADA.

D. Number of animals involved or affected.

V. Drug Experience Report Abstracts or Summaries:

A. Each regular or periodic report must contain copies of currently used package labeling giving full information for use of the drug (21 CFR 514.80(b)(4)). This may include the actual label, the package insert, and the individual carton containing the drug. This labeling must be identical to the latest approved labeling. The examination can be facilitated by noting whether the serial numbers and/or dates of printing are identical.

B. Every regular report must give the amount of product distributed during the reporting interval (21 CFR 514.80 (b)(4)(i)).

C. Data concerning manufacturing or stability is referred to the chemist for his/her review and evaluation.

D. All reports of clinical and animal data may be carefully read and evaluated. These reports include reprints of articles in the scientific literature and studies performed by the firm or its agents. They also contain reports of adverse reactions involving toxicity or lack of effectiveness, and any other data concerning experience with the drug. The reviewer should record all significant information pertaining to the safety and efficacy of the drug. Any information which may be of value in reviewing future supplemental applications, DERs, or any item which has scientific value or potential for such value in future use should be recorded.

E. A general summary of adverse reactions should be included in the form FDA-1932. The information is evaluated by utilizing standardized criteria (Algorithm) and appropriately coded.

F. The coded information concerning each adverse reaction or complaint

received from any source is entered in the computer database in the Division of Surveillance. The records are available to all authorized personnel.

G. Anything unusual in the DER is immediately reported to the Team Leader. A determination can then be made regarding the nature of any action that may be indicated.

H. Reports of adverse reactions for products not the subject of an INAD or NADA are abstracted and filed in the Administrative File for the involved firm. Such reports requiring follow-up action are referred to the Team Leader.

I. The problem drugs which are implicated in serious and more frequent adverse reactions in animals are added to the Division of Surveillance MAR (Monitored Adverse Reaction) list. The MAR committee decides which drugs should be included in the list and assigns priority for detailed review and possible corrective action.