
GENERAL REVIEW AND ENFORCEMENT POLICIES

PROCEDURES FOR PROCESSING DRUG EXPERIENCE REPORTS

I. Purpose:

This document establishes procedures for handling drug experience and adverse reaction reports.

II. Document Control Unit Procedures:

- A. DCU stamps all drug experience reports (DERs) received. Prepares a document tracking sheet by recording the date of the letter, the date it is received, and the name of the firm.
- B. The reports are logged in the STARS I then forwarded to the Division of Surveillance.

III. Drug Experience Reports:

- A. If a DER is received directly by the Division of Surveillance (HFV-210), it is forwarded to DCU for processing according to the procedures listed in paragraph II.
- B. A DER is categorized according to report type and information contained in the submission using DER System Codes. Categories under the system correspond to records and reports information required by 21 CFR 514.80.
 - 1. Report types:
 - a. Code A - Special
 - b. Code B - Regular Six Month
 - c. Code C - Regular Annual
 - 2. Submission types:
 - a. Code A - Up-to-date Report with Supplement
 - b. Code B - Promotional material only
 - c. Code C - without Adverse Reactions

- d. Code D - With Adverse Reactions from Firm
- e. Code E - With Adverse Reactions not from Firm
- f. Code F - Letter Only (Other than Adverse Reactions)
- g. Code G - Other
- h. Code H - Information Previously Requested
- i. Code I - Progress Report on Adverse Reactions
- j. Code J - Product not Marketed/Manufactured
- k. Code K - Manufacturer's Complaint

C. Information not reported as DER:

- 1. Information required under 21 CFR 514.80 but not received as a DER (telephone report of an adverse drug reaction, etc.) will be identified with the appropriate NADA number and forwarded to DCU.
- 2. DCU will code the information in STARS as a DER and forward to the Division of Surveillance for processing.

IV. DER Abstraction:

- A. Upon completion of coding, the DER is assigned to a reviewer within the Division of Surveillance who abstracts information according to the content of the report.
 - 1. DER abstracts are recorded in the STARS II DER review module. The records are then filed by ANADA/NADA numbering the DCU.
 - 2. Adverse reaction reports, submitted as part of the DER, are separated by ANADA/NADA number.
 - 3. The ADR reports are reviewed, coded, and entered into the Division's ADR database.
- B. When action is indicated, the DER is returned to the Team Leader by the reviewer for concurrence. The action is issued by the Division of Surveillance prior to returning the DER to the files.

- C. If it is determined that a supplement or amendment is presently under consideration an extra copy of the abstract is forwarded to the processing Division. All adverse reactions listed for the NADA of the supplement submitted will be available in the Division of Surveillance.
- D. There are no report requirements on Master Files or Food Additive Petitions. Manufacturers of finished feeds are exempt from routine reports requirements of 21 CFR 514.80(b)(4) but are not exempt from the requirements of 21 CFR 514.80(b)(1) and (2) (which are specifically covered under 21 CFR 510.301).
- E. When a master file becomes an NADA, the date of approval of the ANADA/NADA is the anniversary date for reporting DERs.