GENERAL PROCEDURAL POLICIES

INTRA-AGENCY RELATIONSHIP

Intra-agency relations are categorized as formal and informal arrangements.

Formal agreements or understandings may be developed when a continuing working relationship is needed for the orderly conduct of operations.

Such formal written arrangements may be developed for, (1) food additives, (2) methods of analysis, (3) validation of methods, and (4) drug listing and registration, for example.

Informal arrangements are better described as unit to unit or person to person exchanges of information, counsel, opinions or advice during the daily operations. An example is the sharing of information on recombinant DNA technology with the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research.

Effective consumer protection requires coordination and cooperation with all FDA units. The basic responsibilities and authorities of each FDA unit are described in the FDA Staff Manual Guides. Coordination and cooperation between FDA units depends on mutual recognition of the duties, responsibilities and authorities assigned to each unit.

1. **Purpose:**

   This guide establishes the policy and responsibilities for the working relationships with other FDA units.

2. **Policy:**

   a. The policy of the Center is to encourage formal and informal intra-agency arrangements directed toward:

      (1) Mutual understanding,

      (2) More efficient and effective operations.

   b. The Center will cooperate fully with other FDA units.

The Center does not presume on the responsibilities and authorities of other FDA units.

3. Responsibilities:

a. Office of the Commissioner:

(1) The Commissioner provides general direction and policy for the Center.

(2) The Commissioner has redelegated authority to the Director, Center for Veterinary Medicine for the functions regarding NADAs, certification of documents, disclosure of official records, etc. Authority to approve certain supplemental NADAs has been further delegated to the Director and Deputy Director, Office of New Animal Drug Evaluation, and the Director and Deputy Director, Office of Surveillance and Compliance.
Redelegations of authority are codified in 21 CFR 5.20.

(3) The redelegation of authority implies that major and controversial issues will be brought to the Commissioner's attention as a matter of good judgment and administration. This is accomplished verbally and in the form of significant events reporting.

(4) The Office of the Commissioner provides administrative support to the Center through the Associate Commissioner for Office of Management.

b. The Associate Commissioners provide general guidance and agency policy for the Center within specific areas of responsibility:

(1) Regulatory Affairs
(2) Health Affairs
(3) Planning and Evaluation
(4) Public Affairs
(5) Legislative Affairs
(6) Consumer Affairs
(7) Policy Coordination
(8) EEO Activities

4. Other Organizations:

   a. Formal arrangements with other Centers are approved by the Center Director.

   b. Informal arrangements are made by the units or individuals as required.

   c. CVM receives assistance from the Office of Regulatory Affairs in accomplishing field activities.

   d. CVM has formal arrangements with:

      (l) Center for Food Safety and Applied Nutrition regarding clearance of food additives.

      (2) Center for Drug Evaluation and Research regarding liaison with the U.S.P.

5. Regional Offices:

   CVM supports District operations through:

   a. Surveillance of adverse drug reactions
   b. Educational activities
   c. Label review and comments
   d. Emergency Response Program
   e. Case reviews and transmittals
   f. Recall classifications
   g. Program and assignment issuances
   h. Compliance policy issuances
   i. Participation in District and Regional conferences.