GENERAL REVIEW AND ENFORCEMENT POLICIES

PREPARATION OF COMPLIANCE PROGRAMS AND PROGRAM CIRCULARS

Compliance programs and circulars are formally written program plans and instructions which direct and specify the work that is to be done by the Food and Drug Administration's (FDA) field personnel. Compliance programs provide specific guidance to ensure a uniform approach for regulatory/administrative action; to accumulate data (monitoring) on a known problem to determine long-range trends on a statistically valid basis; and to gather product or industry information (make surveys) within a specific time frame to determine the existence or extent of a problem. Program circulars are directed to the field to amend or supplement existing compliance programs, and to provide special program instructions in a problem area for which no compliance program exists and for which one is not deemed necessary or appropriate.

1. Purpose:

   This guide defines and assigns responsibilities for the development, clearance, issuance, and evaluation of compliance programs and program circulars.

2. FDA Policy:

   FDA policy requires that each Center provide definitive guidance to the field organization (ORA) through compliance programs and program circulars for utilizing the resources allocated to it.

3. Responsibility for Program Development:

   New and revised compliance programs and program circulars must be developed in adherence to the schedule agreed upon by the FDA Policy Board. This schedule requires that all programs are to be fully approved and available for implementation by the field before the start of each new fiscal year or in accordance with their scheduled start-up date. Responsibility for development of the programs and circulars is as follows:

   Program Management System (PMS) Manager

      Program Management Systems managers are responsible for assuring that compliance programs and program circulars are developed and resources are allocated for field

activities associated with their respective projects. Specific responsibilities include:

(1) Specifying, in coordination with line managers, compliance program, program circular, and field manpower requirements. This is done during the annul field work planning cycle, approximately fifteen months in advance of the beginning of each fiscal year.

(2) Identifying, through contacts with line organizations, current program needs that can be dealt with by the field organization.

(3) Ensuring that adequate administrative guidelines exist for situations likely to arise in the course of implementation of the program. This may require development and issuance of new administrative guidelines in collaboration with Office Director for Surveillance and Compliance.

(4) Maintaining constant awareness of program progress and difficulties being encountered, and ensuring that program revisions are drafted and communicated to the Division of Compliance (HFV-230) when necessary.

(5) Ensuring that those line managers who may have an interest in the programs are informed of program progress and needs.

(6) Identifying and disseminating, in conjunction with HFV-230, information developed through compliance programs and program circulars to the appropriate organizational elements (headquarters and field) which have need for it or an interest in it.

(7) Ensuring that each terminated compliance program and program circular is evaluated and that each continuing program is evaluated on a yearly basis unless otherwise specified.

PMS CALENDAR OF EVENTS

A. CVM FIELD WORKPLAN

(1) PMS Manager considers issuance of new programs. (October-December)

(2) Workplan preparation procedure begins:

- CVM receives the Call Document from ORA regarding resources. (September)

  - o HFV-220 sends Call Document information to PMS Managers. (October)

  - o PMS Managers responds to HFV-220. (October)

  - o HFV-200, in conjunction with PMS Managers, Field Committee, HFV-220 and HFV-230, decides on final resource allocations. (November)

(3) CVM preliminary workplan sent to ORA. (November/December)

(4) PMS - Manpower Management System projections made by HFV-200, PMS Managers, HFV-220 and HFV-230 in conjunction with HFV-10. (November-December)

(5) Final CVM Workplan sent to ORA. (February)

B. COMPLIANCE PROGRAMS

(1) Compliance Programs written and reviewed. (December-April)

Identify Team

- o CP Manager
- o ORO (Inspections and laboratory branches)

- o CVM program writer (HFV-220/230)
- o Compliance (CVM and ACRA)
- o Field Veterinary Advisory Committee

(2) Reissue Compliance Programs

Categorize as follows:

- o Cat I - editorial changes or no changes (usually no review required by Field Committee)
- o Cat II - minor modifications
- o Cat III - major program modifications

In all cases use the team above for preclearance review purposes.

C. CLEARANCE

- CVM Field Committee and HFC-100 review and comment on programs. Final changes made to programs before issuance. (April-July)
- Cleared programs forwarded to Management Methods Branch (HFA-250) for printing and distribution. (June-August)

D. EVALUATIONS

- Evaluations completed by HFV-220/230 in conjunction with PMS Manager/CP Manager and sent to HFV-200 and HFV-1. (February -August)

E. CVM - ORA FIELD COMMITTEE MEETINGS

- Meetings for the purpose of discussing current fiscal year program problems which may impact on programs to be written in December-April. Other meetings may be held with ORA Field Committee based on availability of parties concerned. (Spring/Fall)