

CENTER FOR VETERINARY MEDICINE
PROGRAM POLICY AND PROCEDURES MANUAL

GUIDE 1240.2202

GENERAL PROCEDURAL POLICIES

VOLUNTARY COMPLIANCE

1. **Purpose:**

This guide describes the types of educational activities undertaken by the Center for Veterinary Medicine (CVM) to encourage increased compliance by the Food and Drug Administration (FDA) regulated firms.

2. **Policy:**

CVM will initiate and participate in discussions, meetings, and other activities to increase understanding of FDA's policies and compliance with the Federal Food, Drug, and Cosmetic Act.

3. **Types of Activities Associated with Voluntary Compliance:**

a. Conferences:

Individual firms or trade associations may request meetings or conferences to discuss problems. The Center's objective in such meetings or conferences is to advise on corrections needed and provide general guidance on how to achieve compliance. (Refer to CVM Guide 1240.2600 Industry Conferences for the policy on setting and holding conferences with industry representatives.)

b. Public Meetings:

Public meetings may provide an ideal forum for stimulating questions and debate. Speeches before various industry and consumer organizations provide an excellent opportunity for the Center to discuss regulatory requirements and expectations. Major changes in Center policy, regulations, or legislation often warrant such forum to explain or clarify the effect of an action or proposed action. In order to provide a basis for logical and reasonable discussions, it is important that the issues or topics be well defined and background information be available to the participants in advance.

c. Symposia and Seminars:

The solutions to many issues facing CVM regulated industries may best be achieved through cooperative efforts coordinated by the Center. The need for these efforts can be identified, positive approaches developed and programs initiated and promoted in public symposia and seminars sponsored by the Center. The Communications Staff, HFV-12 is responsible for developing and implementing these programs.

d. Conventions and trade shows associated with meetings of industry associations provide an excellent opportunity for CVM to promote its programs and initiatives. Having CVM personnel staff an FDA exhibit at a major trade show accomplishes several objectives. It raises industry awareness of FDA; it provides a feedback mechanism based on one-to-one contact with industry in a neutral setting; it allows for the dissemination of information; and it provides an opportunity to learn about current equipment and practices in industry. The Communications Staff, HFV-12, is responsible for coordinating the Center's exhibit program for industry associations.

e. Information/Education:

The Center through its Communications Staff, HFV-12 in the Office of Management and Communications, regularly issues printed publications and informational releases to associations, trade periodicals and educational outlets reaching the industries affected by the Center actions. Additionally, the Staff coordinates an exhibit program for professional organizations. The Staff also produces a subscription publication, FDA Veterinarian, which provides up-to-date information on policies, regulatory activities, drug approvals, upcoming meetings/hearings, etc. to subscribers. The information disseminated through these various channels encourages voluntary compliance by keeping the public informed about CVM regulations and policies.

f. Guidelines:

Various operating units of the Center prepare guidelines on a number of issues as a way of providing guidance to segments of the regulated industry. Availability of new guidelines is announced in the FEDERAL REGISTER and the FDA Veterinarian.

4. Development of Educational Material:

Because of the nature of the educational activities, at any given time any unit or individual within CVM may be asked to assist in the preparation of information materials for industry. However, the Communications Staff, HFV-12 has primary responsibility for overseeing their development.