
GENERAL PROCEDURAL POLICIES

CVM SMALL BUSINESS

Most of CVM's public--the firms affected by its regulations--are, by definition, small business. Regular efforts have been made to reach these firms through their associations, trade press, educational communicators, regulators and other so-called "multiplier" group mailing initiatives of the Industry Information Staff. It is no longer sufficient to use only the established ways of reaching these audiences. As a result of Executive Order 12291 and of the Regulatory Flexibility Act which became effective January 1, 1981, efforts are being made by both FDA and CVM to improve relationships with small businesses and to ensure that Federal regulations do not place an unnecessary burden upon them. coordination of this effort is a function of the FDA Small Business Assistance Program, set up with the Office of Small Business, Scientific, and Trade Affairs within the immediate office of the Commissioner; representatives in each Center; and Small Business Representatives in the field.

1. **Purpose:**

This program provides a mechanism for (1) coordinating CVM activities with those Agency units which are responsible for interacting with regulated small business, and (2) supplying adequate technical and other nonfinancial assistance to small businesses.

2. **Objectives:**

CVM's objectives are: (1) to implement an informational program geared to helping resolve the regulatory responsibilities peculiar to the small business community as it interacts with CVM programs and regulations; and (2) in line with the requirements of the Regulatory Flexibility Act, to objectively and actively consider alternative approaches to CVM regulatory responsibilities which will accomplish CVM objectives while minimizing significant economic impact on small business entities.

3. **Responsibilities for Program Implementation:**

- a. The Director, Office of Management and Communications (HFV-10), serves as the Executive Director of the CVM Small Business Program. He/she is responsible for providing the Center's direction and overseeing the implementation of the program.

- b. The CVM Small Business Coordinator in the Office of Management and Communications serves as the coordinating/operating officer for CVM small business initiative. He/she is responsible for:
 - (1) Working with the Policy and Regulations Team (HFV-6), and with the Office of Small Business, Scientific, and Trade Affairs in developing information/education materials appropriate to the situation.
 - (2) Creating and disseminating information during the information/education phase of the program and handling logistical matters pertaining to this program.

- c. The Team Leader, Policy and Regulations Team is responsible for:
 - (1) Coordinating with the principal author of a regulation the determination of the impact of the regulation on small business community.
 - (2) Providing the CVM Small Business Coordinator with draft and advance copies of relevant regulatory proposals as they are developed.

4. **Information/Education strategy:**

The information/education phase of this initiative involves communication programs designed to address the needs of the small business community and to increase their knowledge of the regulatory process and participation.

Emphasis in this program will be aimed at reaching the affected public by direct mail and through active participation with the ORA Field offices. Efforts will be made to anticipate Agency initiatives and informational needs and to obtain comments and encourage participation of small business through specially-directed mailings. These efforts will be developed in cooperation with the Office of Small Business, Scientific and Trade Affairs and coordinated with educational meetings.

a. Information Methods

Methods employed to interact with small business on a given regulation will depend in part on the assessment of specific impact these regulations will have on small business, on the extent of their potential involvement, and on other impacts such as cost to small business.

b. Information/Education Priority

Of the regulatory areas impacting on small business, some will stand out as appearing to require greater information/education interaction than others--partly because of timing during the fiscal year, partly because of significance to small business and partly due to the Center's priorities. A continuous evaluation process will identify, as the need arises, whether a shift in emphasis is needed under the given circumstances.