CPG Sec. 160.100 Regulatory Actions and Small Business

BACKGROUND:

On September 19, 1980, President Carter signed the Regulatory Flexibility Act, S. 229. This Act delineates procedures for regulatory and informational requirements to ensure that the special needs of small business are considered. Some of the Act's goals are:

To improve the relationship between Government and small business.

To ensure that Federal regulations do not impose unnecessary or undue burdens on small business.

Historically, FDA has always responded to inquiries relating to the enforcement of the laws and regulations it has responsibility to enforce. However, with one exception, it has not sought out those - such as members of the small business community - who might have a greater need for assistance. The exception is the Office of Small Manufacturers Assistance which was established in the Center for Devices and Radiological Health in compliance with Section 10 of the Medical Device Amendments of 1976. This office has an aggressive outreach program for the specific purpose of finding small manufacturers (of medical devices) and helping them comply with FDA regulations. FDA has initiated an agency-wide small business assistance program in accordance with presidential directives issued on June 14, 1978 and November 16, 1979.

The objectives of this program are to:

- Take all feasible steps to minimize the economic impact of regulation.
- Encourage small businesses to participate in the Agency's decision making processes.
- Provide small business with easier access to all levels of the Agency.
- Provide regulatory options which are least costly to small business.
- Help small business to understand and comply with FDA's regulations.

A number of efforts in this program are being implemented through Small Business Representatives (SBR's) working out of the New York, Atlanta, Chicago, and San Francisco regional offices. Firms located outside of the geographical areas of the four SBR's may continue to

contact the nearest FDA district office for information and assistance. They may also direct inquiries to:

Industry Liaison Staff, Office of External Affairs HF-50

5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-6776

Medical device manufacturers should address their requests to:

Division of Small Manufacturers Assistance (DSMA) HFZ-220

1350 Piccard Drive
Rockville, MD 20850
(301) 443-6597

*CFSAN business contact:

Office of Food Safety, Defense and Outreach (HFS-32)

Center for Food Safety and Applied Nutrition

Food and Drug Administration

5100 Paint Branch Parkway
College Park, MD 20740
Email: **industry@fda.gov (mailto:industry@fda.gov)**
Telephone: 301-436-2600*

The Small Business Representatives, the Field Small Business Coordinator, and the FDA district offices are providing the following services:

- Giving technical assistance.
- Clarifying FDA rules and regulations.
- Providing information on proposed regulations and other issues and encouraging small businesses to provide comments and petitions to the Agency.
- Providing information on Agency hearing procedures and how small businesses can participate in hearings.
- Interpreting the laws and regulations as they apply to specific circumstances.
- Suggesting methods of meeting Agency requirements.
- Explaining registration, reporting requirements, and providing the forms.

- Conducting workshops and seminars specifically directed to the problems of small businesses.

At the request of a firm, the SBR may make onsite visits. During these onsite visits, the SBR will review and analyze problems that concern the firm, as well as any problems encountered during the visit. The SBR (or DSMA representative) will explain how the law and regulations apply to these concerns and possible courses of action available to the firm and to the agency.

POLICY:

Onsite Visits

The SBR must submit to the appropriate Regional Food and Drug Director a general summary of each visit. (This summary is available to the public under the Freedom of Information Act.) This informal report will briefly describe the reason for the visit, list the topics discussed, and in the event that the SBR observes violations, describe their characteristics. Although these visits are nonregulatory in nature, they may in some instances result in later compliance inspections.

FDA will continue to assist firms attempting to bring themselves into compliance. Such cooperation provides added assurance that the public will receive safe and wholesome products. Special consideration for the needs of small businesses does not include concessions from compliance with the laws and regulations. All firms, regardless of size, must comply with the laws for which FDA has responsibility.

If a Warning letter has issued, or other regulatory action has commenced against a firm or its product, the firm in question will not be serviced by FDA's small business assistance program. Until such regulatory action is terminated, any information or assistance desired by the firm will be handled by other Food and Drug personnel.

Material between asterisks is new or revised

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