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FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

ADMINISTRATIVE SERVICES

CONSUMER AFFAIRS

CONSUMER AFFAIRS ACTIVITIES

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1. PURPOSE

This Guide identifies the scope of the Food and Drug Administration's consumer affairs activities and sets forth the relevant goals and objectives. It also establishes the pertinent coordination and review procedures.

2. POLICY

Executive Order 12160 identifies standards and strategies for improving the management, coordination and effectiveness of Federal consumer affairs programs. In complying with the Executive Order, the Food and Drug Administration shall increase and monitor public participation in its decision making processes, and assure the public's direct access to the Agency and to officials who have the responsibility for making and interpreting Agency policy at the National and local levels.

3. DEFINITIONS

A. "Public" and "Consumer" as used in this guide are defined as follows.

1. **Advocates.** Individuals or organizations who represent a National public interest in pursuing FDA issues or in seeking corrective measures of Agency actions which have impacted or may have impact on the public.

2. Grassroots. Individuals or organizations who represent local public interest in pursuing FDA issues or seeking corrective measures of

Agency actions which have impacted or may have impact on defined geographical areas.

3. **Special.** Individuals or organizations which represent the interest of special interest groups (e.g., ethnics, women, handicapped, elderly) in pursuing FDA issues or providing input to Agency decisions which have significant impact on target audiences at the National and local levels.

B. Agency Components. As used in this Guide, FDA components are the Offices of the Associate Commissioners, Office of the General Counsel, Executive Director of Regional Operations, the FDA regional and district offices (including resident inspection posts and stations), the bureaus, and the National Center for Toxicological Research.

C. Consumer Affairs Activities. As used in this Guide, consumer affairs activities are all forums for communications or exchanges of information with the public or intended for the public. These activities include but are not limited to:

1. **Formal Processes.**

   a. **Regulations.** Consumers are invited to comment in writing on regulations proposed by the FDA.

   b. **Petitions.** Consumers can petition the FDA for action on a policy or regulation, or comment on the petitions of others.

   c. **Administrative Hearings.** Consumers are invited to contribute testimony at administrative hearings, including regulatory hearings.

   d. **Advisory Committees.** Consumer groups are notified of vacancies on FDA advisory committees and are asked to suggest appropriate nominees.

2. **Informal Processes.**

   a. **National and District Consumer Exchange Meetings.** Held on National and district levels. These meetings are open, informal, and focus on several major policy issues and are chaired by top Agency managers.

   b. **Prehearing Meetings.** Designed to help lay representatives understand scientific and technical information which they may comment on in a subsequent administrative hearing.

c. **Focus Meetings.** Held between Agency personnel and issue-oriented consumer groups or individuals at the request of either party for the purpose of determining perspectives which cannot be readily ascertained through other formal or informal forums.

d. **Priority Process.** An Agency sample of consumer perceptions including suggestions of what FDA's top five priority areas should be.

e. **Consumer Inquiries, Complaints, and Correspondence.** The Agency's responses to consumer inquiries and correspondence (telephone and written) enables direct dialogue with interested consumers regarding regulated products as well as the Agency's mission, programs, and policies. Through this type of activity, the Agency receives and measures consumer opinions, concerns, and perceptions. The Agency handles consumer complaints through its field offices and Headquarter units. (Investigations of consumer complaints have led to action against harmful or dangerous FDA-regulated products).

f. **Pilot Public Reimbursement Program.** Applicants are reimbursed for participating in certain administrative hearings. Applicants are screened by an Agency Evaluation Board chaired by the Associate Commissioner for Consumer Affairs.

g. **Education Programs and Activities.** Consumers are provided opportunities to become aware of the Agency's mission and regulatory process, administrative practices and procedures as well as how to effectively access the Agency. In addition, skill training opportunities are available for qualified consumers to enhance their participation in advisory committee proceedings.

h. **Bureau Initiated Consumer Education and Information Programs.** Consumer awareness programs are conducted which focus on toxins, food labeling, food additives, drugs (prescription and OTC), medical devices, radiation, etc. These programs are implemented by Consumer Affairs Officers located in FDA regional and district offices.

4. RESPONSIBILITIES

Associate Commissioner for Consumer Affairs (ACCA) will serve as the Agency focal point to:

1. Develop the Agency's Annual Consumer Affairs Plan and Budget Exhibits and outreach initiatives, and develop relevant consumer perspectives for inclusion in Agency decision-making activities.

2. Determine the extent to which the Agency's Consumer Affairs Plan supports the Agency's objectives and program requirements, for forwarding to the Commissioner for review and approval.

3. Maintain liaison with, and coordinate information from, the bureaus and other Agency components about significant public interest issues in their respective areas.

4. Maintain a dialogue with the public by contacting and involving the public (specialized advocates and grassroots groups) in Agency consumer affairs activities.

5. Analyze consumer feedback at the National and local level to determine major health issues and trends in consumer concerns, in order to understand the consumer's perspective of Agency regulatory policies and activities.

5. CONSUMER AFFAIRS PLAN

A. General. Four months prior to the beginning of each fiscal year (June) the Associate Commissioner for Consumer Affairs (ACCA) will forward to the Commissioner for approval a comprehensive Agency-wide consumer affairs plan. This plan will detail the annual Agency consumer affairs activities and resources. It will cover all activities in support of the Agency's goals, and objectives as described in this Guide and in support of initiatives which the Commissioner elects to track through the plan.

B. Scope of Plan. The scope of the consumer affairs plan covers FDA activities which are designed to:

1. Collect and analyze information about interests and concerns and to provide consumers with mechanisms for participating in Agency decisions. The data collected includes information that is needed to properly carry out effective public participation programs (consumer risks, needs, attitudes, and desires associated with FDA policies, programs, and regulated products).

2. Provide consumers with information to enable them to safely and effectively use Agency-regulated products. The information is conveyed through consumer education activities.

3. Enhance consumer understanding of FDA's mission, program, and policy decisions. This information is conveyed through Agency announcements and publications, responses to consumer inquiries, press releases, speeches, and FDA conducted meetings.

C. Goals. The Consumer Affairs Plan shall be based on the following goals:

1. Generating public dialogue and exchange of views in order to improve Agency decision making.

2. Systemizing consumer affairs strategies for components.

3. Explaining the Agency's management of public funds for consumer affairs activities.

4. Increasing the public's confidence and involvement in the Government.

5. Informing the public of the available benefits and services and learning from the public through public reactions to FDA regulatory activities.

6. Advising Agency policy makers of consumer needs, interests, and concerns.

D. Objectives in Support of Goals. The objectives in support of the goals shall be based on the following:

1. Generating public dialogue and communications by:

   a. Providing the consumer with sufficient and timely opportunities to enhance active participation in shaping Agency policies and priorities.

   b. Creating a public awareness of the interrelationship between policy development, regulation, and education.

   c. Clarifying and conveying to appropriate audiences the scope and complexity of regulating products that fall within the Agency's regulatory jurisdiction. Conveying the Agency's range of methods, resources, and authorities to protect the public health.

2. Supporting program strategies and operational objectives by:

   a. Continuing to improve the quality, timeliness, impact, and effectiveness of education and training programs intended to increase public awareness of significant health and regulatory

issues; and providing the necessary skills and knowledge to the public to enhance the degree and quality of participation.

b. Achieving broader understanding of Agency programs, policies, priorities, and legislative initiatives among employees, beneficiaries, target audiences, State, local, and private institutions.

c. Upgrading the quality of publications designed for special target and improving; the strategy and programs for their distribution, and evaluating the effectiveness of these materials.

3. Acting as Agency/public liaison by:

a. Explaining to a variety of audiences how FDA spends its appropriations and the results of those expenditures.

b. Informing the public on the efficiencies and effectiveness resulting from integration of programs to achieve special objectives.

4. Improving confidence in the Government by:

a. Achieving broader public understanding of those programs that work in the public interest and why.

b. Seeking public understanding of the constraints of many Agency programs in order to avoid unrealistic expectations by the public.

c. Encouraging the public to take an active role in determining which consumer priorities fall within the mandate of FDA.

5. Providing beneficiary information by:

a. Informing the public of its right to access the Agency.

b. Increasing system efficiency by improving communication with the public on how and where to access the Agency in a proper and complete manner.

c. Increasing the level of individual awareness through systematic communication, i.e., education/training programs and mass media.

d. Evaluating the impact of consumer affairs activities based on the following criteria:

(1) General appraisal overall focus of individual activities to enhance consumer education and participation.

(2) Review of consumer affairs priorities and the allocation of resources against the total need.

(3) The extent to which the plan meets consumer needs as stated in the Agency's goals, objectives, and the priority setting process.