SMG 3280.1

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION:

INFORMATION RESOURCES MANAGEMENT

DIRECTIVES MANAGEMENT

FDA ADMINISTRATIVE DIRECTIVES

Effective Date: 01000/2005 Channed 10/20/2005

NOTE: This SMG is being revised

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Attachment A - Subject Categories and Responsible Offices

Attachment B - Form FDA 2006, Clearance

Attachment C - Guidelines for Writing

Dissectives:

1. PURPOSE

This Guide establishes procedures for issuing administrative policy. procedures, and instructions in the form of directives relating to functions and operations of the Food and Drue Administration. These directives are written to implement Department of Health and Human Services (HES) instructions. to set forth FDA organizations and delegations of authority, and to develop procedural guidance when HHS has not covered the subject.

2. DEFINITIONS

A. Directive. A directive is a written communication issued in an organized. system to establish policy, procedures, responsibilities or organization; to require action; or to set forth information needed for the effective operation.

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United States. General Accounting Office

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Staff Manual Guide Transmittal No. ... United States. Food and Drug Administration, 1992-05 FDA/ORA International Inspection Manual and Travel Guide United States. Food and Drug Administration. Division of Emergency and Investigational Operations, 1997 Answers to Questions on Selected FDA Bureau of Biologics' Regulation **Activities** United States. General Accounting Office, 1980 **Administrative Practices and Procedures** United States. Food and Drug Administration Affirmative Action Plan United States. Public Food and Drug Administration, 1979 Health Service, 1978 FDA Veterinarian .1983 Pocket supplement to Preamble compilation, administrative practices Federal Register ,1988 and procedures United States. Food and Drug Administration,1979 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2013 United States. Congress. House. Committee on Appropriations. Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related **Equal Employment Opportunity Plan** United States. Food and Drug Administration, 1978 Agencies, 2012 Merit Systems Reporter ,1985 Speeding Up the Drug Review Process, Results Encouraging, But Progress Slow United States. General Accounting Office, 1981 Food, Drug, Cosmetic Law Reporter, 1963 Food and Drug Law Richard M. Cooper,1991 NIH Guide for Grants and Contracts ,1978 **NIH Guide for Grants and Contracts** National Institutes of Health (U.S.),1979 The Medical Device Industry Norman F. Estrin, 1990-08-31 Practical information about the complexities of biomedical technology and regulation and their implications for manufacturers and marketers of health care devices Written primarily for those in the industry concerned about staying competitive in light of complex and fluctuating regulatory approach Use of Advisory Committees by the Food and Drug Administration United States. Congress. House. Government Operations Committee, 1974 **Use of Advisory Committees by the Food and Drug** Administration United States. Congress. House. Committee on Government Operations, Intergovernmental Relations A Legislative History of the Federal Food, Drug, and Cosmetic Act and Its Amendments United Subcommittee.1974 States, 1979

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