

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

INFORMATION RESOURCES MANAGEMENT

DIRECTIVES MANAGEMENT

FDA ADMINISTRATIVE DIRECTIVES

Effective Date: 01/10/2005

Changed: 10/20/2005

NOTE: This SMG is being revised

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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 Drug Administration. These directives are written to implement Department of Health and Human Services (HHS) 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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