U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Introduction

PURPOSE

The purpose of the Compliance Policy Guides (CPG) Manual is to provide a convenient and organized system for statements of FDA compliance policy, including those statements which contain regulatory action guidance information. The statements made in the CPG are not intended to create or confer any rights, privileges, or benefits on or for any private person, but are intended for internal guidance.

BACKGROUND

The CPG Manual system was initiated in 1968 in order to establish an orderly method for assembling and maintaining statements of policy and was first issued in 1969 by the Bureau of Compliance. In 1972, the responsibility for its maintenance was assigned to the Division of Field Operations, Office of the Executive Director of Regional Operations. In November 1984, the offices of the Associate Commissioner for Regulatory Affairs and the Executive Director for Regional Operations were combined and reorganized. As a result, the responsibility for directing and coordinating the preparation and maintenance of the CPG Manual was assigned to the newly formed Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs.

CONTENTS

The CPG Manual is the repository for all agency compliance policy that has been agreed to by the center(s) and the Associate Commissioner for Regulatory Affairs. Examples of sources from which CPGs are prepared include: a) statements or correspondence by headquarters offices or centers reflecting new policy or changes in compliance policy including Office of the Commissioner memoranda, center memoranda and other informational issuances, agency correspondence with trade groups and regulated industries, and advisory opinions; b) precedent court decisions; c) multicenter agreements regarding jurisdiction over FDA regulated products; d) preambles to proposed or final regulations or other Federal Register documents; and f) individual regulatory actions.

RESPONSIBILITY

OFFICE OF REGULATORY AFFAIRS (HFC-1)

The Associate Commissioner for Regulatory Affairs (ACRA) (HFC-1) approves all new or substantially revised CPGs prior to their issuance. Final clearance for rescinding a CPG generally is provided by the ACRA. An exception to the requirement for ACRA clearance may be made if the basis for rescission was previously published in the Federal Register. In this situation, the director of the Division of Compliance Policy (HFC-230) can authorize the rescission.

OFFICE OF ENFORCEMENT - DIVISION OF COMPLIANCE POLICY (HFC-230)

Review the policy in the CPG Manual on a continuing basis to assure that it is current. Coordinate the preparation of new or revised CPGs with the Center(s), ORA headquarters and field offices, and the Office of General Counsel. Obtain any necessary clearances for new

policy statements or changes in existing compliance policy and obtain final approval, and ensure that a Federal Register notice of availability is prepared for new and substantially revised (including rescinded) CPG.

Control and assign numbers for CPG. Prepare the camera copy of CPG Manual and forwards it to the Management Methods Branch (HFA-250) for publication.

Notify the field and other offices as soon as possible when a new or substantially revised CPG becomes effective or when a CPG is rescinded. The effective date of new or substantially revised CPG is the date that the CPG is approved by the ACRA, unless otherwise stated in the CPG or a Federal Register notice announcing availability of the CPG.

CPGs having a revision date of the month and year of the bound edition are revised CPGs with this publication. The index shows the current status of all prior and current CPGs under the heading Compliance Policy Guides.

CENTERS AND HEADQUARTERS OFFICES

Review policy in the CPG Manual to assure that it is current. Identify new and developing compliance policies that are significant enough to be articulated and disseminated to the field and industry. Center and headquarters offices will cooperate with the Division of Compliance Policy (HFC-230) in the formulation and clearance of individual CPG.

OFFICE OF INFORMATION RESOURCES MANAGEMENT - INFORMATION COLLECTION AND DISSEMINATION BRANCH (HFA-250)

Process Manual issuances for printing. Serves as the Agency's contact with the National Technical Information Services (NTIS), U.S. Department of Commerce, Springfield, VA 22161 which makes the Manual available to the general public for a fee.

FORMAT OF CPG

TITLE: A clear concise statement of the subject of the CPG.

BACKGROUND: Information concerning the problem or situation addressed by the CPG. Whenever possible, the original source of the policy statement or change will be cited. When the CPG contains a change in existing policy, the background should indicate the original policy and the reason for the change.

POLICY: A clear and concise statement of the current FDA policy. Whenever any limitations on, or exceptions to the stated policy are necessary, those limitations and exceptions will be stated.

REGULATORY ACTION GUIDANCE: Whenever possible, each CPG will contain regulatory action guidance. This section will include the necessary guidance for making regulatory decisions and should include, but is not limited to, the following information: a) the limits at which the field is authorized to take direct regulatory action without referral to the appropriate center; b) information for use in making decisions as to admissibility of imports; c) information on products, processes, or conditions for which there is insufficient experience or data to warrant delegation of authority for direct regulatory action by the field; and d) recommended charges (specimen charges) for direct regulatory actions.

CPG NUMBERING SYSTEM

The CPG Manual utilizes both a "Section" and a "CPG" number for individual Guides. The CPG numbers are preceded by CPG and have numbers in the range of 7100-7199. The CPG numbers were based on the previous organization of the CPG. The Guides have been reorganized into new chapters and Section numbers now indicate the chapter and location within the chapter. The Section numbers precede the title of each Guide while the CPG numbers follow the title in parentheses.

CLEARANCE PROCEDURE

Any new or substantially revised CPG must be cleared by the originating center, other offices or centers affected, and by the ACRA. The Division of Compliance Policy (HFC-230) will coordinate and maintain all clearance records.

DISTRIBUTION

For FDA personnel, printed copies of the Compliance Policy Guides are no longer available. Visit **http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116791.htm (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116791.htm)** to view them online.

For state and local government agencies personnel, copies may be obtained by contacting the State Information Branch, (HFC-151), Division of Federal-State Relations at (301) 443-6200.

Issuances of new or revised CPGs between Manual publications will be electronically available to FDA personnel. NTIS will be provided with a printed copy of all new or revised CPGs for distribution to the general public for a fee.