Foreword: Compliance Policy Guides (CPGs)

Compliance Policy Guides (CPGs) explain Food and Drug Administration (FDA) policy on regulatory issues related to FDA laws or regulations. They advise FDA's field inspection and compliance staffs, as well as the industry, as to the Agency's strategy and policies to be applied when determining industry compliance. Compliance Policy Guides may derive from a request for an advisory opinion, from a petition from outside the Agency, or from a perceived need for a policy clarification by FDA personnel.

The field staff is continually encouraged to contact the Office of Policy and Risk Management (OPRM), within the Office of Regulatory Affairs (ORA) when they need clarification on an existing CPG or see a need for a new CPG. The Office of Policy and Risk Management is committed to providing the needed guidance.

Please send comments or suggestions for improvement to the Food and Drug Administration, Office of Regulatory Affairs, Office of Policy and Risk Management, 10903 New Hampshire Avenue, WO 32, Suite 4300, Silver Spring, MD 20993 (email:OPRMExecOpsAssignments@fda.hhs.gov. As usual, we appreciate all comments and suggestions.

Katherine N. Bent, RN, PhD Assistant Commissioner for Compliance Policy (ACCP) Director Office of Policy and Risk Management

Please refer to <u>SMG 7100.1: FDA Staff Manual Guides, Volume IV - Agency Program Directives (/downloads/AboutFDA/ReportsManualsForms/StaffManual-Guides/UCM509012.pdf)</u> for more information.

More in <u>Compliance Policy Guides</u> (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm)

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Chapter 1 - General

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Chapter 2 - Biologics

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Chapter 3 - Devices

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Chapter 4 - Human Drugs

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<u>Chapter 5 - Food, Colors, and Cosmetics</u> (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119194.htm)

<u>Chapter 6 - Veterinary Medicine</u> (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm117042.htm)