
GENERAL REVIEW AND ENFORCEMENT POLICIES

**ASSESSMENT OF COMPLIANCE POLICY GUIDES (CPG)
AFFECTING VETERINARY PRODUCTS**

The Compliance Policy Guides (CPG) Manual is designed to provide a system for the issuance, filing and retrieval of official statements of FDA Compliance Policy. The CPG Manual is issued by ORA, Division of Field Operations. Input to the CPG Manual is an important Center for Veterinary Medicine (CVM) function.

1. Purpose:

This document defines the responsibilities for developing draft Compliance Policy Guides for issuance by ORA in the Compliance Policy Guides Manual.

2. Content of Compliance Policy Guides:

Compliance Policy Guides provide headquarters policy guidance to the field offices. Guides may contain but are not solely limited to the following:

- (1) Policy guidance which supplements, complements, or emphasizes guidance in compliance programs or for which there is no specific compliance program. Background information is included in each guide to explain the policy.
- (2) Regulatory tolerances, guidance, and authorization for direct action by the field offices without referral to the appropriate center in the areas of seizure, citation, and warning letter.
- (3) Information for use in making decisions as to the admissibility of imports.

3. CVM Responsibilities for Compliance Policy Guides Development:

- a. The Division Director of Compliance, in coordination with the Division of Compliance, is responsible for ensuring that Compliance Policy Guides are planned, assessed, written, revised, and terminated, when necessary.
- b. The Director, Office of Surveillance and Compliance, is responsible for final written approval of draft CPGs and for forwarding them to ORA for final clearance and issuance by FDA.
- c. The Division of Compliance, as approved by its Division Director, is responsible for creating, maintaining, and orchestrating working groups to assess the need for and to

produce draft Compliance Policy Guides.

- d. The Division of Compliance will facilitate and initiate interactions within the working group to discuss, assess, plan and write draft Compliance Policy Guides as well as revise and terminate Compliance Policy Guides.
 - e. The Division of Compliance will invite agency personnel (including representatives from CVM, ORA, CDER, and CFSA) to participate as members of the working group, as needed for effective assessment and draft production of Compliance Policy Guides.
 - f. The Division of Compliance, in coordination with the working group, will provide recommended draft Compliance Policy Guides to the Division Director, as agreed upon by a majority consensus within the working group.
 - g. The Division Director will provide revisions, as necessary. The Division of Compliance, in coordination with the working group, will discuss, accept or reject, and amend the recommended draft Compliance Policy Guides until a final consensus is met between the Division Director and the working group. Once a consensus is met, the recommended draft Compliance Policy Guide becomes the Approved Draft Compliance Policy Guide.
 - h. The Division Director will forward the Approved Draft Compliance Policy Guide to the Office of the Director. The Office of the Director will provide revisions, as necessary. The Office of the Director, in coordination with the Division Director, will discuss, accept or reject, and amend the documents until a final consensus is met between the Division Director and the Office of the Director. The final documents are then officially transferred to the Office of the Director for routing and required signatures by ORA, the CVM Director of Policy, the CVM Director of Office of Surveillance and Compliance, the CVM Office of the Center Director, Office of General Counsel, and the Director of ORA. After all signatures are secured, a Federal Register Notice of availability will be published and the final CPG will be published on the ORA website.
4. Processing Procedures:
- Detailed information on guideline format, clearance, printing and distribution is provided in the Compliance Policy Guidance Manual.