GENERAL REVIEW AND ENFORCEMENT POLICIES

DEVELOPMENT OF COMPLIANCE POLICY GUIDES AFFECTING VETERINARY PRODUCTS

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

1. Purpose:

   This guide defines the responsibilities for developing 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 and guidance, and authorization for direct action by the field 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. Center Responsibilities for Policy Guides Development:

   a. Division Directors, in coordination with the Division of Compliance, are responsible for ensuring that Compliance Policy Guides are planned, written, and revised when necessary.

   b. The Director, Office of Surveillance and Compliance is responsible for final written

approval of guides and for forwarding them to ORA for final Agency clearance and issuance.

c. Division Directors are responsible for periodically reviewing existing Compliance Policy Guides with a view to making revisions or terminating those which are no longer required.

4. Processing Procedures:

Detailed information on guideline format, clearance, printing and distribution is provided in the Compliance Policy Guides Manual.