

CPG Sec. 450.100 CGMP Enforcement Policy - OTC vs Rx Drugs

BACKGROUND:

Because of increased visibility and promotion of certain OTC preparations, there are periodic inquiries from division offices within the Office of Pharmaceutical Quality Operations (OPQO) regarding whether or not the enforcement policy for CGMP regulations is the same for OTC drug products as it is for prescription (Rx) drug products.

Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act requires drugs to be manufactured in conformance with current good manufacturing practice. This section does not differentiate between OTC and Rx products and it was not intended by Congress to do so.

A prescription drug may be toxic or have other potential for harm, which requires that it be administered only under the supervision of a licensed practitioner (section 503(b)(1) of the Act). For this reason, problems associated with its manufacture are generally more likely to cause serious problems.

POLICY:

The CGMP regulations apply to all drug products, whether OTC or prescription.

REGULATORY GUIDANCE:

The selection of an enforcement action to be applied will be based on the seriousness of the deviation, including such factors as potential hazard to the consumer.

Issued: 4/1/82