Inspections, Compliance, Enforcement, and Criminal Investigations

CPG Sec. 400.200 Consistent Application of CGMP Determinations (CPG 7132.12)

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BACKGROUND:

In recent years there has been a growing number of commitments made by FDA to various programs and systems designed to ensure the quality of drug products by carefully monitoring drug manufacturers' compliance with the Current Good Manufacturing Practice (CGMP) regulations. FDA has for many years enforced CGMP as part of its overall drug quality assurance program. The approval process for drug marketing applications (original and abbreviated new drug applications and antibiotic Forms 5 and 6) includes a review of the manufacturer's compliance with the CGMP. More recently, FDA has assumed additional roles in the area of assurance of drug quality involving good manufacturing practice through such programs as the Government-Wide Quality Assurance Programs for drug purchase contracts by the Department of Defense and the Veterans Administration, and the Maximum Allowable Cost program of HHS. Decisions regarding compliance with CGMP regulations are based upon inspection of the facilities, sample analyses, and compliance history of the firm. These data are summarized in profiles which represent several years of history of the firms. In consideration of the growing number of programs dependent upon CGMP assessment, Agency policy must be consolidated in regard to approval or disapproval of drug marketing applications, government purchasing contracts, etc., and the relation of such determinations to regulatory action.

POLICY:

CGMP deficiencies supporting a regulatory action also support decisions regarding non-approval of drug marketing applications, government purchasing contracts, candidates for MAC, etc. Therefore, the issuance of a *warning* letter or initiation of other regulatory action based upon CGMP deficiencies must be accompanied by disapproval of any pending drug marketing application, or government contract for a product produced under the same deficiencies.

Similarly, disapproval of any drug marketing application, government contract, etc., based upon CGMP deficiencies must be accompanied by regulatory and/or administrative action against any other product produced under the same conditions. *Material between asterisks is new or revised*

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