Inspections, Compliance, Enforcement, and Criminal Investigations

CPG Sec. 410.100 Finished Dosage Form Drug Products in Bulk Containers - Applications of Current Good Manufacturing Practice Regulations (CPG 7132a.06)

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BACKGROUND:

Questions have arisen concerning the application of the "umbrella" CGMP regulations, 21 CFR Parts 210 and 211 to firms which prepare dosage form drug products in bulk containers, such as tablets in fiber drums, and sterile antibiotic powders in bulk containers. Drug products in such bulk quantities are usually intended for further repacking into conventional retail packages such as bottles of 100 tablets each or vials of an antibiotic powder for reconstitution. These questions of application have, on occasion mistakenly expanded the term "bulk drug" to mean not only ingredients of drug products but also finished dosage forms in large quantities. However, in order to apply Parts 210 and 211 it is important to distinguish drug products in finished dosage forms in bulk containers from bulk drug components (i.e. ingredients intended for use in manufacturing or processing of a drug product.)
POLICY:

The CGMP regulations set forth in 21 CFR Parts 210 and 211 apply to the preparation of finished dosage forms regardless of whether such drug products are in bulk containers or retail packaged form. This is set forth in 21 CFR 210.3 (b)(4) and 211.3(a).

The CGMP regulations do not apply as binding regulations to bulk drug components. They are to be used as guidelines during the inspection of facilities manufacturing drug components (43 FR 45026, TP 42a, 9-29-78).

Material between asterisks is new or revised

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