Inspections, Compliance, Enforcement, and Criminal Investigations

CPG Sec. 430.200 Repacking of Drug Products - Testing/Examination under CGMPs (CPG 7132.13)

Sec. 430.200 Repacking of Drug Products - Testing/Examination under CGMPs (CPG 7132.13)

BACKGROUND:

Questions have periodically arisen regarding how various testing and/or examination requirements under the CGMP regulations (21 CFR Parts 210 and 211) are to be applied to repackers of finished dosage form drugs. In particular, there have been questions regarding whether it is appropriate to apply various "component" requirements in the CGMPRs (such as those under Section 211.84 concerning identity testing and analysis or receipt of a report of analysis for purity, strength, and quality) to finished dosage form drugs which an establishment receives and repackages. It has also been questioned how the requirements under 211.165 are to be applied to repackers, insofar as the requirements for appropriate laboratory determination for identity and strength of each active ingredient prior to release are concerned.

We have carefully considered the suitability of applying the requirements concerning "components" in the CGMPRs to repackers of finished dosage form drugs. Due to the definitions of "component" under 210.3(b)(3) and "drug product" under 210.3(b)(4), we have concluded that the requirements for "components" under Part 211 cannot be suitably applied to finished dosage form drugs which are received by an establishment and repackaged without alteration to the "drug product" itself.

In the preamble to the final order for the CGMP regulations, it is pointed out in regards to a manufacturer that there is no intent under 211.165(a), once the product is in its finished dosage form, to require potency testing of both the bulk and packaged drug product phases, and that manufacturers could choose to do potency assays at either phase (43 FR 45062, paragraph 389). We believe a similar principle is applicable to drug product repackers; where the manufacturer of the finished dosage form in a bulk container is required to perform appropriate analytical testing for all appropriate specifications, including the identity and strength of each active ingredient, we do not consider it necessary for the repacker to repeat such testing upon such drug products he receives and repacks with label declarations consistent with those on the bulk container and without altering the properties of the finished dosage form product.
POLICY:

Generally, we do not consider the CGMP regulations (21 CFR Parts 210 and 211) to require repackers of finished dosage form drugs to perform analytical testing such as chemical identity tests or assays, or to require receipt of reports of analysis, on a batch-by-batch basis for drug products which are repacked under the following circumstances:

1. The incoming bulk containers of finished dosage form drug products are received in intact, undamaged containers which are completely and properly labeled as received, and there is no reason to suspect they have been subjected to improper storage or transit conditions prior to receipt;

2. The repacking operations are conducted under conditions which assure that the properties of the incoming drug product are not altered;

3. The repackaged containers are labeled with the same substantive labeling declarations (e.g. identity, strength, and directions for use) concerning the properties and use of the drug product which are consistent with the labeling on the incoming bulk containers.

Under such circumstances we consider that requirements for appropriate specifications and testing/examination procedures for repacked drug products will be met by an appropriate system involving examination of the labeling and sufficient organoleptic examination of the drug product to confirm its identity in accordance with corresponding specifications established by the repacker.

The policy in this Compliance Policy Guide applies only to the question of adequate batch-to-batch testing/examination criteria for routine acceptance and release of drug products which are repacked. It does not alter any testing which repackers may be required to perform on drug products from other standpoints, such as any stability testing required in order to establish appropriate expiration dates in the container-closure system used by the repacker, testing which may be required to determine the suitability of the repacker's drug product containers and closures, testing which may be necessary to establish appropriate time limits for the completion of each phase of production, or

testing which may be required on non-penicillin drug products for the presence of penicillin.

Issued: 7/1/81