Inspections, Compliance, Enforcement, and Criminal Investigations

CPG Sec. 450.550 Control and Accountability of Labeling Associated with Tamper-Resistant Packaging of Over-the-Counter Drug Products

BACKGROUND:

Final rules (21 CFR 211.132) were published in the Federal Register on November 5, 1982 (47 FR 50442) (As corrected in 48 FR 1706) to provide tamper-resistant packaging requirements for certain OTC drug products.

Questions have been raised as to whether or not those parts of tamper-resistant packaging which may contain labeling, such as shrink seals imprinted with the product name, need to be controlled and reconciled, under the CGMP regulations. Questions have also been raised on the degree of control and accountability needed for parts of tamper-resistant packaging which may be part of the immediate container closure system or some other portion of the packaging.

POLICY:

Those portions of tamper resistant packaging which contain labeling, as defined in Section 201(m) of the FD&C Act, will be considered as any other labeling and, as such, are subject to the control and accountability provisions of Subpart G of the Current Good Manufacturing Practice Regulations.

Those portions of tamper-resistant packaging which contact the drug product are considered part of the container closure system and, as such, are subject to the control and accountability provisions of Subpart E of the CGMP regulations.

Those portions of tamper-resistant packaging which do not fall into the above categories will be considered as general packaging material, subject to the general controls for packaging contained in Subpart G of the CGMP regulations.

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Links on this page: