

Inspections, Compliance, Enforcement, and Criminal Investigations

CPG Sec. 425.200 Computerized Drug Processing; Vendor Responsibility (CPG 7132a.12)

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BACKGROUND:

Computer systems used in the production and control of drug products can consist of various devices (hardware) and programs (software) supplied by different vendors, or in some cases by a single vendor. It is important that such computer systems perform accurately and reliably, *and* that they are suitable for their intended use.

Questions have arisen as to the vendor's responsibility in assuring computer systems performance and suitability. When an integrated system, composed of elements from several different vendors, fails, it can be especially difficult to attribute the cause of a problem to one particular vendor.

POLICY:

The end user is responsible for the suitability of computer systems (hardware and software) used in manufacture, processing or holding of a drug product.

The vendor may also be liable, under the FD&C Act, for causing the introduction of adulterated or misbranded drug products into interstate commerce, where the causative factors for the violation are attributable to intrinsic defects in the vendor's hardware and software. In addition vendors may incur liability for validation, as well as hardware/software maintenance performed on behalf of users.

Material between asterisks is new or revised

Issued: 1/18/85

Revised: 9/4/87