CPG Sec. 160.750 Drug and Device Products (Including Biologics and Animal Drugs) Found in Violation of GMPRs - Reconditioning

BACKGROUND:

The question has arisen as to whether drug and device products that have been produced or held by methods or under conditions not in accordance with Good Manufacturing Practice regulations, and consequently determined to be adulterated, may be reconditioned and returned to trade channels. Situations covered by this CPG are those in which a &quotformal" judgment of adulteration has been rendered e.g., drug and device products that have been seized and condemned pursuant to Section 304 of the Act due to Good Manufacturing Practice deficiencies, drug and device products that have been recalled because they were found to be in violation of the CGMPRs, etc. Although GMP deficiencies can be corrected in subsequent batches or lots of the involved product(s), it may be difficult or impossible to correct the effect of the deficiencies retrospectively in batches or lots already produced.

POLICY:

The reconditioning of drug and device products found to be adulterated as a result of having been produced, processed, or held under conditions which are deficient with regard to Good Manufacturing Practice regulations may be approved providing all of the following conditions are met as follows:

1. Any reconditioning proposal must be reviewed by all parties concerned (District, Center, OE, *OCC*) to determine whether the plan can reasonably be expected to bring the drug device product(s) into compliance.
2. In order to be acceptable, a proposed reconditioning plan must overcome any observed GMP deficiencies and correct any known product defects present.
3. If the lot to be reconditioned is held within the facility where the GMP violations occurred, the violative conditions must be corrected in advance of accepting a reconditioning proposal, or included as part of the reconditioning proposal.
4. If the lot is held in a facility separate from the one in which the GMP violations occurred and the

separate facility is in compliance, a reconditioning proposal can be considered as provided for in paragraphs 1 and 2 above.

No product shall be released until all reconditioning commitments are fully met as verified by FDA.

Material between asterisks is new or revised

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More in Compliance Policy Guides (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm)

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