

Inspections, Compliance, Enforcement, and Criminal Investigations

CPG Sec. 444.100 Recovery of Investigational New Drugs from Clinical Investigators (CPG 7132c.05)

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POLICY:

We will regard the retrieval of investigational new drugs from clinical investigators by the sponsor of the IND/INAD or his agent as stock recoveries. As such, these actions will not be included in the FDA Weekly Report of Recalls.

Having considered the issue of "recall" of investigational new drugs, whether precipitated by product defect, disqualification of the individual investigator, discontinuation or completion of a particular clinical study, or termination of the entire IND/INAD, we concluded that the appropriate classification for any such action is "stock recovery."

Recall, as defined in the Regulatory Procedures Manual, Part 5, applies to situations where the violative product has already entered distribution channels and thus is no longer under the direct control of the manufacturer or primary distributor.

The term "stock recovery", as defined in the RPM, is better applied to the return of investigational new drugs, as the sponsor of the IND/INAD continues to exert direct control over the drug during the investigational period.

The use of "recall" in 21 CFR 312.1(a)(7), 312.1(d)(12), 312.9(c)(2), and 511.1(d)(2) is, therefore, inappropriate as these CFR sections deal with the retrieval of investigational drugs for which the primary distributor (sponsor) retains full accountability and direct control.

We are obligated to make public all recalls. In direct conflict to this are other FDA regulations which protect the confidentiality of an ongoing investigational study.

For the above reasons, all investigational new drug product recoveries should be classified as "stock recovery" since the sponsor continues to exert direct control over the stocks. The agency is not obligated to make these actions public, but could exercise its discretion to do so if such recovery is the result of full termination of the INDA/INADA.

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