

## **Inspections, Compliance, Enforcement, and Criminal Investigations**

### **CPG Sec. 400.900 Class I Recalls of Prescription Drugs (CPG 7132.01)**

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#### **BACKGROUND:**

A Class I recall is an emergency situation involving removal from the market of a product in which the consequences are immediate or long-range, life threatening, and involve a direct cause-effect relationship. Class I recalls can, if necessary, require retrieval of the recalled article from consumers (users). The pattern of distribution of prescription drugs to consumers is different from that of other articles. Retrieval of drugs when in the possession of consumers must take into consideration the doctor/patient relationship.

#### **POLICY:**

When there is a Class I recall of a prescription drug, retail level consignees (retail, hospital, nursing home pharmacists) will be required to review their prescription files for the appropriate time period consistent with the period of distribution of the drug, in order to identify all customers to whom the recalled drug was dispensed. The pharmacist must notify those customers' physicians of the specific problem, and keep a record of the physician notifications. The physician will be responsible for deciding whether his patients are to be contacted.

If the pharmacist cannot distinguish in his prescription records between those customers to whom the lot(s) of recalled drug was dispensed, and those who received the same drug from a lot not under recall, or from a different manufacturer, then the pharmacist, as a precautionary measure, must notify the physicians of all customers who received the drug.

If retail level consignees (pharmacists, hospitals, dispensing physicians) cannot identify persons to whom a drug under Class I recall was dispensed, there must be a warning issued by FDA to the general public.

Issued: 10/1/80