

CPG Sec. 130.200 Inspection of Firms when Legal Action is Pending

BACKGROUND:

Inquiries from the field have indicated there is some confusion on whether or not to reinspect a firm while legal action is pending against that firm.

POLICY:

Reinspection of a firm should be based upon public health considerations. FDA has an obligation to determine compliance with the law even if a case is pending, and if on reinspection further violations are found, to take additional steps as necessary to bring about correction.

It must be clearly understood that cessation of a violation is not grounds for dismissal of a case. Prosecution actions particularly are based on violations that have already occurred, and nothing that takes place after the violation changes that fact.

Where a court requests, reinspection is also appropriate. A district should always be in a position to furnish the court with current information covering the defendant's operations. This does not mean, however, that FDA should perform an inspection of each firm just prior to arraignment or trial. As already indicated, unless a court requests an inspection, reinspection at that time is based upon public health considerations in light of priorities and available manpower.

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