

# CPG Sec. 160.400 \*Section 305 Meeting\* Before Report of Criminal Violation

## BACKGROUND:

Section 305 of the Act states: "Before any violation of this Act is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding."

A similar provision was incorporated in the 1906 Act. This subject is also covered by regulation under 21 CFR 7.84, 7.85, and 7.87.

\*Section 305 procedures have been used as a warning in order to induce corrective action. Such use solely for purposes of warning in order to induce correction is contrary to the purpose of Section 305, and should not be used in lieu of other procedures to achieve corrective action.\*

## POLICY:

\*Section 305\* should be used only when initiation of prosecution is actually being considered by the agency.

\*Material between asterisks is new or revised\*

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**Foreword: Compliance Policy Guides (CPGs)**  
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**Chapter 1 - General**  
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