

CPG Sec. 160.500 Answering Inquiries on Status of Criminal Referrals

BACKGROUND:

Potential criminal cases are frequently preceded by an opportunity for proposed defendants to present their views on whether a criminal action should be forwarded to the United States Attorney. It is not unusual for prospective defendants, their attorney, and/or their representative to contact district headquarters offices subsequent to the Section 305 meeting to inquire about the agency decision and status of the case. The following policy applies to such inquiries from such persons.

POLICY:

1. The inquirer may be advised, if it is true, that a decision was reached not to forward a case for prosecution.
2. If the inquirer is confirmed to be the subject of the potential referral (or a representative of a subject) and the proposed case has not as yet been forwarded to the Department of Justice, advise the inquirer the case is still under consideration. Avoid identifying the unit handling the case at that time (i.e. district, center, *Chief Counsel,* or Commissioner's office).
3. If the subject of the potential referral wishes to submit additional facts, be guided by 21 CFR 7.85 (g). If the inquirer wishes a meeting to present such facts, the Agency may want to meet with the individual if it will not unduly delay processing of the matter. Inform the inquirer that we will give appropriate consideration to what other facts are presented that have a direct bearing on the case. Any such meeting with a person previously accorded an opportunity to present views under Section 305 will be considered an extension of that opportunity.
4. Once a case has been referred to the Department of Justice the matter is no longer in the hands of the Agency. It is then the prerogative of the Department of Justice to determine what contacts to have with the proposed defendant. Do not reveal to an inquirer that any matter has been referred to the Department of Justice unless FDA's Office of Chief Counsel has confirmed that the referral may be revealed. Inform the inquirer that the case is still under consideration and notify the *Office of General Counsel* of the communications.

Material between asterisks is new or revised

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