

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

EXTERNAL RELATIONS

**MEMORANDA OF TELEPHONE CONVERSATIONS AND MEETINGS WITH
NON-FDA PERSONS**

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1. PURPOSE

This Guide provides for the preparation and distribution of memoranda of telephone conversations and/or meetings with persons outside the FDA (See 21 CFR 10.65 and 10.70). This Guide also includes procedures for directing such memoranda to the administrative file and distributing copies to affected Agency Headquarters and field offices. Such matters include decisions, statements of policy, advice, or conclusions to which future reference may be required and as such these matters must be made a part of the administrative record.

2. POLICY

All FDA officials holding meetings or telephone conversations with non-FDA persons during which significant matters are discussed are required to prepare, maintain, and distribute a memorandum of such discussion in accordance with the following guidelines.

3. PREPARATION GUIDELINES

Memoranda of meetings or telephone conversations with persons outside FDA should be short, clear, and concise statements of decisions, policy, advice, or other important information discussed. General discussions, arguments, etc., need not be included. Information and format required for uniformity in reporting follows:

1. Date. Insert the date of the meeting or telephone conversation.
2. Type of Contact. Specify whether telephone conversation or meeting.

3. Participants. List the name, title, and affiliation of each non-FDA participant. Also include the name, title, and mailing symbol for each FDA participant.
4. Subject. List only the main topic of the meeting or telephone conversation.
5. Time and Location. Identify the time and office location of the meeting or telephone conversation.
6. Decisions, Policy, Advice or Action. Provide a brief statement of any significant matters discussed. Such matters include decisions, policy issues, advice, and follow up actions taken.
7. Signature. The signature of the preparer.
8. Other Affected Headquarters or Field Office(s). List the mailing symbol for field or Headquarters offices which may be affected by significant matters discussed with persons outside FDA.

4. DISTRIBUTION OF MEMORANDA

FDA officials holding meetings or telephone conversations with persons outside FDA will prepare memoranda and distribute appropriate copies of such memoranda to affected Headquarters and field offices. If minutes of specific meetings or telephone conversations or other documents are available, such documents should be attached to the memoranda. In addition, the preparer will ensure that appropriate documentation of decisions, opinions, or minutes of meetings are directed to the administrative file in accordance with 21 CFR 10.70.