OFFICE OF EXECUTIVE PROGRAMS

Obtaining the Services of an Expert or Fact Witness for Criminal Cases

CONTENTS

PURPOSE

- This MAPP describes the procedures in the Center for Drug Evaluation and Research (CDER) for handling the designation of expert or fact witnesses requested by the Office of Criminal Investigations (OCI) or the Office of Chief Counsel (OCC) for criminal cases.

BACKGROUND

- Expert or fact witnesses can be physicians, scientists, engineers, consumer safety officers, or other professionals who, by virtue of their training, experience, or education, are considered authorities within their specialized field or who possess information related to a specific issue of interest. Expert witnesses differ from fact witnesses in that they are provided great freedom to express their opinions about relevant matters that fall within their individualized area of expertise. However, the principal consideration in the identification and selection of an expert or fact witness is the nature of the individual's testimony, not the professional standing of the witness.

- In general, the requests for expert or fact witnesses will be primarily focused within one or more of the following categories:

(1) Product-specific issues. These could include, for example, the pharmacologic effects, mechanism of action, common side effects, and/or risks associated with a specific drug product; approved indications, dosing and administration, and approval status of a specific drug product.

(2) Compliance/enforcement issues only. These might include, for example, the regulatory status of foreign drugs, personal or other importation of drug products,

regulatory status of "old" drugs, enforcement strategies related to marketed unapproved drugs, regulatory issues related to compounded drug products. Generally, fact and expert witnesses would not testify about whether or not the law has been broken but would testify about what the provisions of the Food, Drug, and Cosmetic Act (the Act) and the regulations at issue require.

(3) Product specific and compliance/enforcement issues.

(4) General regulatory policies and procedures (e.g., absence of general recognition, drug development or regulatory procedures, GMP issues).

REFERENCES

- Memorandum – August 25, 2003 "Obtaining Services of and Paying for Expert Witnesses/Consultants – Policy"
- Staff Manual Guide: 2610.2 "Obtaining Services of Expert or Fact Witnesses"
- Manual Guide: DCP#95-037 "Expert Witnesses"

DEFINITIONS

- **Expert Witnesses**: Physicians, scientists, or other professionals who are considered authorities in their specialized field. The principal consideration in the identification and selection of an expert witness is the testimony, not the professional standing of the witnesses.

  An individual qualifies as an expert witness when testimony covers opinions based on hypothetical situations, diagnosis, unique analysis of facts, or development of conclusions (all of which involve technical experience, competence, or specialized knowledge). Deduction, or an application of special knowledge, is expert testimony.

- **Fact witnesses**: Those who give testimony on the facts relating to specific instances or occurrences (e.g., testimony regarding chain of custody of a package purchased in an undercover buy, the regulatory and/or approval status of a drug, the registration and/or listing status of a manufacturing firm).

POLICY

- Appropriate and timely identification and selection of expert and/or fact witnesses is required for adequate case preparation. As soon as possible after a criminal investigation has been initiated, the agent assigned to a case will determine whether scientific, medical, compliance, regulatory, or other testimony will be required. This will assist CDER in identifying and selecting the most appropriate expert or fact witness for an individual case in a timely manner.

- To the extent possible, CDER will provide internal Agency expert or fact witnesses for criminal cases when requested by OCI or OCC.

- If an outside (non-FDA) expert or fact witness will best serve the interests of the Agency in a particular case, CDER will work with OCI and/or OCC to identify and select the best expert or fact witness for the case.

- Whenever possible, declarations or affidavits from CDER in lieu of live testimony should be encouraged.

RESPONSIBILITIES AND PROCEDURES

Office of Criminal Investigations (OCI)

- OCI and/or OCC will contact the Executive Operations Staff (EOS) as soon as the need for a witness is identified and will follow with a formal (i.e., written or e-mail) request for the assistance of EOS in identifying and selecting an appropriate expert or fact witness to support an OCI and/or an OCC investigation. This request will include the following information (see Attachment A):
  (1) Names of the Agent (OCI contact person), Assistant U.S. Attorney (AUSA), and OCC attorney assigned to the case
  (2) District in which the case will be tried/prosecuted
  (3) A brief summary of the case including the laws violated
  (4) A specific description of the type of expertise needed for the case
  (5) Anticipated dates and location of the trial, if known.

Executive Operations Staff (EOS)

- EOS will work with OCI and/or OCC and the principal investigator/agent to obtain sufficient specific information about the case to determine the type of witness needed.

- EOS will consult the Office of Compliance to determine the type of witness needed.

- Once the type of witness needed is determined, the EOS will solicit the name of a potential Agency witness from the appropriate office. For example, if the primary type of witness needed is a clinician with knowledge of a particular drug product, the Office of New Drugs would be contacted and asked to try to identify an appropriate internal witness for the case.

- If an internal witness is identified, the EOS will provide the name of the witness to OCI and/or OCC.

- If the Center is unable to accommodate the request or if EOS and the Office of Compliance determine that the most appropriate expertise for the case does not exist within the Center, EOS will inform OCI and/or OCC as soon as possible. If an internal witness cannot be identified and an outside consultant must be used, the consulted office will recommend a potential expert for the case and EOS will make

the initial contact with the expert to ensure availability. CDER, OCI, and OCC will jointly decide which office will be designated to take the lead role in working with the outside consultant to prepare for the case.

- Once a witness or external expert has been identified, that witness will be referred to OCI and/or OCC for case preparation.

Office of Compliance

- The Office of Compliance will assist EOS in determining the appropriate expert or fact witness for a criminal case.

- If the witness identified for the case is not from the Office of Compliance, the Office of Compliance will aid OCI and OCC in preparing the witness, if needed.

Consulted Office

- Any CDER employee who receives a direct request from a source other than EOS for an expert or fact witness should forward the request to EOS.

- When an office is contacted by EOS regarding the need for a witness, the consulted office will provide the name of a witness to EOS in a timely manner.

Office of Chief Counsel (OCC)

- When contacted by an OCI agent about a criminal case, OCC will work with the OCI agent to determine the specific violations charged in the case and complete the Request for Expert Witness form (see Attachment A).

- Once a witness or external expert for a criminal case has been identified, OCC will work with the witness or external expert to prepare for testimony.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

ATTACHMENT A

REQUEST FOR EXPERT WITNESS
(THIS FORM SHOULD BE COMPLETED BY THE OCI AGENT IN CONSULTATION WITH OCC)

Name of Agent: _____

Date of Request: _____

AUSA assigned to case: _____

Has OCC been contacted about this case? ___ Y ___ N

If yes, OCC attorney assigned to case: _____

District in which case will be prosecuted: _____

Anticipated date of trial: _____

Brief summary of case, including name of the specific drug product(s) involved, how the product is being administered and used, and the specific violations charged in the case:

_____

_____

_____

_____

_____

Provide a specific description of the questions the witness will need to answer or issues the witness will need to address during testimony:

Question or Issue #1: _____
_____
_____
_____

Question or Issue #2: _____
_____

_____

Question or Issue #3: _____
_____
_____
_____

Please complete and forward this form either electronically or by hard copy to the OCI Headquarters CDER Senior Operations Manager.