SMG 2127.2

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

EXTERNAL RELATIONS

REQUESTS FOR TESTIMONY OF FDA PERSONNEL IN NON-FDA PROCEEDINGS

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1. PURPOSE

This guide establishes procedures for handling the following requests for the testimony of FDA personnel in non-FDA proceedings, including judicial, administrative, and legislative proceedings:

1. Requests from private parties

2. Requests from other Federal government agencies

3. Requests from state and local government agencies

4. Requests from state and local legislative bodies

2. DEFINITIONS

A. Testimony means testimony by written statement, by declaration under penalty of perjury, by affidavit, by deposition, interrogatory, or by appearance at the proceeding. Affidavits that identify documents for purposes of certifying records for Freedom of Information Act requests are not considered testimony for purposes of this guide. Questions regarding whether a particular affidavit is subject to these instructions should be referred to the Division of Compliance Policy (HFC-230).

B. Request means any written request, invitation, notice of deposition, letter rogatory, court order, or subpoena, except for subpoenas intended solely for the production of records.

3. REFERENCE

21 CFR 20.1

4. POLICY

FDA's policy regarding testimony by FDA employees is expressed in 21 CFR 20.

FDA will usually decline to authorize any employee to testify unless compelling circumstances exist, including but not limited to the following:

1. FDA is the only source of the factual information requested;

2. Records containing the requested information are not available to certify for admission in the proceeding; and

3. It is in the public interest to interrupt the employee's duties in the implementation and enforcement of laws subject to FDA jurisdiction, and it is consistent with the policies, program responsibilities, and objectives of FDA.

4. The testimony is determined to be in the public interest and will promote the objectives of FDA and the laws it enforces.

It ordinarily is considered not to be in the public interest to interrupt the duties of FDA personnel in the implementation and enforcement of the laws subject to the agency's jurisdiction in order to participate in proceedings to which FDA is not a party. Ordinarily, FDA seeks to maintain strict impartiality with respect to private litigants.

Testimony requested by Federal, state, and local governments is often, but not always, deemed to be in the public interest.

No FDA employee may provide testimony pertaining to any FDA function or with respect to any information acquired in the discharge of his or her official duties unless properly authorized to do so.

FDA generally will bear the costs associated with any testimony that is authorized. FDA will return checks and vouchers for witness fees to the requester by certified mail. On a case by case basis, FDA may determine that

it is appropriate to accept payment from other government agencies for some or all of travel costs associated with testimony they request.

5. RESPONSIBILITIES

A. Director, Office of Enforcement (HFC-200) is responsible for authorizing approval or providing disapproval for the testimony of FDA personnel in non-FDA proceedings. (The Associate Commissioner for Regulatory Affairs, pursuant to 21 CFR 5.20(b) and 20.1(c), has designated the Director, Office of Enforcement to perform these functions.)

B. Division of Compliance Policy, Office of Enforcement (HFC-230) is responsible for staff work regarding testimony requests from other Federal government agencies and from private parties and for coordinating with the Division of Federal-State Relations regarding testimony requests from state and local officials.

C. Division of Federal-State Relations, Office of Regional Operations (HFC-150) is responsible for staff work regarding testimony requests from state and local government agencies and state and local legislative bodies.

D. Freedom of Information Staff (HFI-35) is responsible for handling subpoenas intended solely for the production of records and for assisting the Division of Compliance Policy and the Division of Federal-State Relations by providing records responsive to a subpoena duces tecum (21 CFR 20.2) or other requested records related to testimony requests.

E. Other headquarters and field offices are responsible for assisting the Division of Compliance Policy and the Division of Federal-State Relations in evaluating requests regarding testimony by their employees and testimony pertinent to their respective responsibilities. When appropriate, they are responsible for identifying suitable individual(s) to testify and for drafting the authorized testimony.

F. Office of General Counsel (GCF-1) is responsible for providing guidance and assistance in legal aspects of handling testimony requests, including review and preclearance of affidavits and other types of testimony in written form, assistance in witness preparation, and assistance during the testimony, as requested.

G. FDA employees who receive verbal or written requests for testimony are responsible for advising the requester of the requirements of 21 CFR 20.1 for testimony requests to be submitted to the agency in writing and for employees to obtain authorization from the Commissioner, prior to providing testimony. A copy of any memorandum of telephone conversation or letter documenting such communication should be

forwarded to the Division of Compliance Policy. Alternatively, FDA employees may refer the requester to the Division of Compliance Policy. FDA employees should not indicate any commitment regarding availability or willingness to testify in any particular case, prior to an agency determination that authorization for testimony will be granted.

H. The office of any FDA employee who is authorized to provide testimony generally is responsible for funding travel and other expenses associated with providing the testimony. If the office lacks sufficient funds for the authorized testimony, it should contact the appropriate administrative officer to request funding assistance.

6. PROCEDURES

A. Testimony requests should be submitted in writing well in advance of the desired testimony date in order to allow time for evaluating and processing the requests. Requests should include the following information: hearing body, date, location, and purpose of the proceeding; the nature and scope of the testimony FDA is being asked to provide and the use to which it will be put; the name(s) of the FDA employee(s), if known, being asked to testify; the requester's interest in the matter sought to be disclosed; and a discussion of the requester's rationale for considering that the testimony is in the public interest and will promote the objectives of FDA and the laws it enforces. Oral testimony requests will not be honored unless they are reduced to writing in compliance with 2l CFR 20.l.

B. FDA headquarters and field offices that receive written testimony requests should alert the Division of Compliance Policy (HFC-230) by telephone, upon receipt of the request, and should forward the request by FAX or other expeditious means to that office.

C. Written requests for testimony should be sent to:

U.S. Food and Drug Administration
Office of Enforcement
Division of Compliance Policy (HFC-230)
5600 Fishers Lane
Rockville, MD 20857
Phone: (301) 443-1500
FAX: (301) 594-0114

D. The staff work to be performed by the Division of Compliance Policy and the Division of Federal-State Relations in processing testimony requests includes:

1. Evaluating the request, in consultation with other agency components, the Office of General Counsel, and/or other government agencies, as appropriate, and

2. Preparing a response to the testimony request for issuance by the Director, Office of Enforcement.

E. The Division of Federal-State Relations will forward the recommended response to the Director, Office of Enforcement through the Director, Office of Regional Operations.

F. Employees authorized to present testimony should seek legal guidance from the Office of General Counsel and technical guidance from appropriate FDA unit(s), prior to presenting the testimony. Affidavits and other testimony in written form should be reviewed by the Office of General Counsel except for affidavits attesting only to the absence of records or when the testimony authorization memo provides otherwise. Subsequent to presenting the testimony, the employee should submit a summary or copy of their testimony or a transcript of the testimony to the Division of Compliance Policy. This office will review the summary and distribute copies within the agency, as appropriate. If the testimony is authorized at any hearing before a state or local legislative body, the summary memo should address not only the individual's testimony, but also any other portions of the hearing attended.

G. Ordinarily, FDA will first determine if agency records are available that will provide the requester with the information that is being sought. If records are available, FDA ordinarily will offer to provide the requester with certified copies of the records, in lieu of testimony. This may be done either by the Division of Compliance Policy, the office receiving the request, or the Office of General Counsel, as determined on a case-by-case basis.

H. If the requestor will accept copies of FDA records in lieu of testimony, the request may be processed as a Freedom of Information Act (FOIA) request. (If the testimony request is not specific enough for FOIA purposes, the requester should be told to submit a separate FOIA request. Alternatively, a memorandum of telecon clarifying the request may be prepared and forwarded with the testimony request to the Freedom of Information Staff.) The Division of Compliance Policy will forward the testimony request, together with an explanatory memorandum or note, to the Freedom of Information Staff (HFI-35) for logging and assignment. The Division of Compliance Policy will notify the component FOIA officer(s) about the FOIA request and about any special processing instruction, such as the need for certified copies of records or the time frames for processing.

I. If a subpoena for an FDA employee to provide testimony is to be denied, the Division of Compliance Policy will consult with the Office of General Counsel to determine if a motion to quash or other legal step is appropriate. If appropriate, the Office of General Counsel and/or the Division of Compliance Policy will work with the U. S. Attorney's office in the jurisdiction of the court.

J. A subpoena duces tecum (or similar request for an FDA employee both to appear and to provide agency records) shall be handled both as a testimony request (21 CFR 20.1) and as a FOIA request (21 CFR 20.2.)

7. TESTIMONY REQUESTS COVERED BY OTHER GUIDANCE

A. DHHS Inspector General and Office of Equal Employment Opportunity

This guide does not cover requests from the DHHS Inspector General or from the DHHS Office of Equal Employment Opportunity for affidavits or other statements. The DHHS Standards of Conduct require all employees to "assist the [DHHS] Inspector General and other investigative officials in the performance of their duties or functions. This requirement includes the giving of statements or evidence to investigators of the Inspector General's office or other DHHS investigators authorized to conduct investigations into potential violations." (45 CFR 73.735-302(d))

Employees who receive such requests from the DHHS Inspector General may contact the Division of Ethics and Program Integrity (HFA-20). Employees who receive such requests from the DHHS Office of Equal Employment Opportunity may contact the FDA Office of Equal Employment Opportunity and Civil Rights (HF-l5).

B. FDA's own proceedings

Testimony in judicial or administrative proceedings to which FDA is a party (either directly or indirectly because DHHS is a party) is considered part of one's official duties and special authorization is not required. Employees who receive a testimony request from one of the other parties to the proceeding should notify the assigned FDA or DHHS attorney as soon as possible, as well as supervisors and others in the chain of command with a need to know.

C. Congressional testimony requests

See Staff Manual Guide FDA 2l27.l.

D. Subpoenas intended solely for the production of records

Such subpoenas are handled as FOIA requests in accordance with 2l CFR 20.2 and Staff Manual Guide 2460.7.

E. Testimony as a Private Citizen

Some testimony as a "private citizen" may raise special concerns such as possible conflict of interest or may require approval as an outside activity. Employees should refer to the Standards of Ethical Conduct for Employees of the Executive Branch 5 CFR Part 2635.805. For further guidance, contact the Division of Ethics and Program Integrity (HFA-20) for guidance.

F. Former FDA employees

Requests for the testimony of former FDA employees are not covered by 21 CFR 20.1. However, FDA may assist former employees with respect to testimony requests. Former employees are encouraged to contact either the Division of Compliance Policy or the Division of Federal-State Relations, as appropriate, if they receive a request or subpoena to provide testimony regarding FDA-related matters.

Former employees must be aware that there may be other restrictions on their ability to provide the requested testimony, including possible conflict of interest concerns and statutory and regulatory restrictions on the release of trade secrets and other kinds of confidential information.

8. SUPERSESSION

This supersedes Staff Manual Guide FDA 2127.2 dated May 29, l979 (GT No. 7).