SMG 2127.2

FDA Staff Manual Guides, Volume III - General Administration

External Relations

Requests for Testimony of FDA Personnel in Non-FDA Proceedings

Effective Date: 10/18/2021

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 ORA's Division of Information Disclosure Policy (orainfoshare@fda.hhs.gov).

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. Generally, 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, ORA Office of Strategic Planning and Operational Policy (OSPOP) is delegated the authority to approve or provide disapproval for the testimony of FDA personnel in non-FDA proceedings in accordance with SMG 1410.24, Disclosure of Officials Records and Authorization of Testimony (Authority transferred from Division of Compliance Policy to OSPOP through reorganization of functions in accordance with SMG 1410.1).

B. ORA Division of Information Disclosure Policy (DIDP), OSPOP is responsible for staff work regarding testimony requests from other Federal government agencies and from private parties. ORA DIDP is also responsible for staff work regarding testimony requests from state and local government agencies and state and local legislative bodies.

C. Freedom of Information (FOI) Staff in ORA and all Centers are responsible for handling subpoenas intended solely for the production of records (state subpoenas). A state subpoena for records will be denied and converted to a FOIA request by FOI Staff and will be answered in accordance with the Freedom of Information Act (FOIA).

D. All Centers and ORA headquarters and field offices are responsible for assisting ORA's DIDP 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.

E. Office of Chief Counsel (OCC) 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.

F. FDA employees who receive verbal or written requests for testimony are responsible for forwarding the request to ORA DIDP testimony specialists at orainfoshare@fda.hhs.gov. All requests for testimony must be made in accordance with the requirements of 21 CFR 20.1 and be submitted to the agency in writing. 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.

G. 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 Centers, ORA headquarters and field offices that receive written testimony requests should alert ORA's DIDP by forwarding the request via email to orainfoshare@fda.hhs.gov.

C. Written requests for testimony should be sent to:

U.S. Food and Drug Administration
Office of Strategic Planning and Operational Policy
Division of Information Disclosure Policy
12420 Parklawn Drive
Element Bldg., Rm. 4042
Rockville, MD 20857
orainfoshare@fda.hhs.gov

D. The staff work to be performed by ORA's DIDP in processing testimony requests includes:

1. Evaluating the request, in consultation with other agency components, the OCC, and/or other government agencies, as appropriate;

2. Collaborating with the assigned OCC attorney, if the testimony request is authorized; and

3. Preparing and forwarding the recommended response and authorization (if approved) to the Director, OSPOP for signature.

E. Employees authorized to present testimony should seek legal guidance from the OCC attorney assigned to the case 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 OCC attorney assigned to the case, except for affidavits attesting only to the absence of records or when the testimony authorization memo provides otherwise.

F. 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 generally will offer to provide the requester with certified copies of the records, in lieu of testimony. This may be done either by ORA's DIDP or OCC, as determined on a case-by-case basis.

G. If the requestor will accept copies of FDA records in lieu of testimony in FEDERAL court, the Testimony Specialist will work with the appropriate Center FOI personnel to obtain the records and have them certified. If the testimony is in STATE court, FDA can deny the testimony without offering records. If FDA determines that is appropriate to offer records in lieu of testimony in state court, the same process is followed as in federal court.

H. If a subpoena for an FDA employee to provide testimony is to be denied, which is only allowed for state court subpoenas, or if a motion to quash or other legal step is appropriate for federal court, ORA DIDP will consult with OCC. If appropriate, OCC and/or ORA DIDP will work with the U. S. Attorney's office in the jurisdiction of the court.

I. 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 and ORA DIDP as soon as possible, as well as supervisors and others in the chain of command with a need to know.

D. Congressional testimony requests See Staff Manual Guide FDA 2127.1 Subpoenas intended solely for the production of records

Such subpoenas are handled as FOIA requests (if in a state court) in accordance with 2l CFR 20.2. If in a federal court, ORA DIDP works with the appropriate Centers, ORA headquarters, and field offices as well as OCC.

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 ORA DIDP or OCC, 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 November 11, 1993.

9. Effective Date

The effective date of this guide is October 18, 2021.

10. Document History – SMG 2127.2, "Requests for Testimony of FDA Personnel in Non-FDA Proceedings"

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approval Official
Initial	10/12/2021	N/A	Lisa Bellows, Director Division of Information Disclosure Policy	Steven Tave, Director, Office of Strategic Planning and Operational Policy