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**POLICY AND PROCEDURES**

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**OFFICE OF EXECUTIVE PROGRAMS**

**Special Government Employees Representing Sponsors Before CDER**

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**PURPOSE**

This MAPP outlines Center for Drug Evaluation and Research (CDER) policy and procedures when a current CDER Special Government Employee (SGE) seeks to represent a sponsor before the Food and Drug Administration (FDA) about a specific application.

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**BACKGROUND**

The FDA uses medical and scientific experts as SGEs to provide independent and objective advice on critical issues facing the agency. These SGEs are a vital and necessary component of the drug review process, providing the Agency with essential services. Many of these experts are clinical investigators who are actively involved in the development of new drugs. These experts are sometimes placed in the position of representing industry on a product before the FDA.

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**POLICY**

- Nearly all Federal employees are prohibited from representing parties on applications that are pending before the Government.

- CDER SGEs, may, under some circumstances, legally represent sponsors in meetings with the FDA. Representing a sponsor includes, for example, sitting in the sponsor's section during a meeting or serving as a presenter, discussant, or responder. Permissible representation may occur in internal private meetings with CDER as well as public meetings such as advisory committee meetings.
- Although such representational activities may be allowed, SGEs must avoid any appearance of a conflict of interest and avoid situations in which it would appear that they are using their government position for private gain.
- Current SGEs are exempt from this general prohibition if they work for the government no more than 60 days during the immediately preceding period of 365 consecutive days<sup>1</sup> and were never involved with the specific matter as part of their FDA duties.
- A current SGE is prohibited by law from representing a sponsor before FDA, if a SGE worked more than 60 days for the government during the immediately preceding period of 365 consecutive days<sup>2</sup>, or if the SGE has ever worked on the specific matter in question for the FDA.
- If a current SGE has worked for the government 60 days or less during the immediately preceding 365 consecutive days, CDER will decide on a case-by-case basis whether it is appropriate for the SGE to undertake such representational activities. In making that determination, CDER will consider the following factors:
  1. **The role of the SGE in the development of the drug:** SGEs with long-term, in-depth knowledge of the development of the drug and who possess detailed technical knowledge of the drug are more likely to be allowed to represent a sponsor than an SGE who had little involvement with the drug. This is especially true when the SGE has knowledge that is essential to the success of the meeting and where replacement of the SGE would be difficult. For example, if the SGE was the principal investigator on a pivotal trial, CDER is more likely to allow the requested representation than if the SGE was a consultant hired to help the sponsor prepare for a meeting with FDA.
  2. **The length of time the SGE worked on the specific matter:** The longer the SGE has worked on the specific matter for the sponsor, the more likely CDER is to allow the requested representation. This is especially true when the SGE involvement with the specific matter predated his or her appointment as an SGE.
  3. **The relationship of the requested representation to the regular duties of the SGE:** When the meeting does not involve the advisory committee on

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<sup>1</sup> Counted from the day of the meeting.

<sup>2</sup> Counted from the day of the meeting.#

which the SGE sits, then CDER is more likely to allow the requested representation.

- CDER retains the discretion to place limits on the requested representational activities of its SGEs. For example: 1) CDER could limit the representational activities of an SGE to discussing only the trial in which he or she served as principal investigator, or 2) CDER could limit the SGE to speaking only about the personal work of the SGE.
  - A current SGE may not represent a sponsor in any meeting with the FDA without the written approval of the Division of Advisory Committee and Consultant Management (DACCM). Current advisory committee standing members are further restricted from representing sponsors in any capacity before their own advisory committee without written permission from the Center Director.
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## RESPONSIBILITIES

### The SGE:

1. Notify DACCM of and request approval for the proposed representation at least four weeks prior to the meeting and before agreeing to represent a sponsor in any meeting with the FDA.
2. Provide DACCM with a brief description of the present and past relationship to the sponsor and the application under consideration<sup>3</sup>. This may be done via email.
3. Recuse himself or herself from any meeting with the FDA if 1) a SGE worked for more than 60 days during the immediately preceding 365 consecutive days, or 2) has ever worked on the specific matter for the FDA.

### DACCM:

1. Notify the appropriate CDER division and office of the SGE's requested participation. Ask the division and office to confirm whether the SGE has worked on the specific matter for FDA.

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<sup>3</sup> This description should include information such as, but not limited to, the duration of the SGE's relationship with the sponsor, the duration of the SGE's work on the product/application, the SGE's role in development of the drug, any payments received by the SGE, and the status of the SGE's relationship to the sponsor and product/application (past, ongoing, prospective).

2. If the Division, Office, and DACCM disagree on whether it is appropriate for the SGE to attend a meeting, the matter will be forwarded to the Center Director for resolution.
3. Inform the SGE and the appropriate CDER Division and Office of the decision via email.

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## PROCEDURES

1. At least four weeks prior to the meeting, before agreeing to represent a sponsor in any meeting with the FDA, the SGE notifies DACCM of the request for approval of the proposed representation.
2. SGE provides DACCM with a brief description of the present and past relationship to the sponsor and the application under consideration, via email
3. SGE recuses himself or herself from any meeting with the FDA if 1) the SGE worked for more than 60 days during the immediately preceding 365 consecutive days, or 2) has ever worked on the specific matter for the FDA.
4. DACCM notifies the appropriate CDER division and office of the SGE's requested participation. DAACM asks the division and office to confirm the SGE's history of working on the specific matter for FDA.
5. The division and office confirm whether the SGE has worked on the matter and offer an opinion as to whether the proposed representation is appropriate.
6. If the Division, Office, and DACCM disagree on whether it is appropriate for the SGE to represent the sponsor at a meeting, the matter will be forwarded to the Center Director for resolution.
7. DAACM informs the SGE and the CDER Division and Office of the decision via email.
8. Following the meeting, both the SGE and the Division shall maintain record of the SGE's representation of the Sponsor in this matter.

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## REFERENCES

1. 5 C.F.R. Part 2635 Standards of Ethical Conduct for Employees of the Executive Branch
2. 18 U.S.C. 202 Definitions
3. 18 U.S.C. 203 Compensation to Members of Congress, officers, and others in matters affecting the Government

4. 18 U.S.C. 205 Activities of officers and employees in claims against and other matters affecting the Government
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**DEFINITIONS**

**Special Government Employee.** A person appointed on a full-time, part-time, or intermittent basis to perform temporary duties and serve with or without compensation for not more than 130 days during any period of 365 consecutive days.

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**EFFECTIVE DATE**

- This MAPP is effective upon date of publication.
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**CHANGE CONTROL TABLE**

Effective Date	Revision Number	Revisions
4/22/1996	Initial	n/a
9/16/22	Rev. 1	<ul style="list-style-type: none"><li>• Changed language to align with statute and regulation.</li><li>• Clarified the MAPP applies to current SGEs only.</li><li>• Updated process, timelines, and changes in technology.</li></ul>