REVIEW MANAGEMENT

SPECIAL GOVERNMENT EMPLOYEES REPRESENTING SPONSORS BEFORE CDER

CONTENTS

PURPOSE This MAPP outlines current Center for Drug Evaluation and Research (CDER) policy and procedures when Special Government Employees (SGEs) seek to represent sponsors before the Food and Drug Administration (FDA) about particular applications.

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.

REFERENCES

- 5 C.F.R. Part 2635
- Standards of Ethical Conduct for Employees of the Executive Branch
- 18 U.S.C. 201
- 18 U.S.C. 208

DEFINITIONS

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

POLICY

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

- SGEs are exempt from this general prohibition as long as they work less than 60 days in any period of 365 consecutive days and were never involved with the specific matter as part of their FDA duties.

- CDER consultants, experts, and advisory committee members can, under some circumstances, legally represent sponsors in meetings with the FDA. Representing a sponsor includes sitting in the sponsor's section during a meeting. This includes 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.

- A SGE is prohibited by law from representing a sponsor before FDA, if a SGE worked more than 60 days for the government in any period of 365 consecutive days or if the SGE has worked on the particular matter for the FDA that he or she wishes to represent.

- If the SGE has worked less than 60 days in the previous 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. <u>The role of the SGE in the development of the drug:</u> 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 representational activities than if the SGE were a consultant hired to help the sponsor get ready for the meeting with FDA.

2. The length of time the SGE has worked on the particular matter: The longer the SGE has worked on the particular matter, the more likely CDER is to allow representational activities. This is particularly true when the SGE involvement with the particular matter predated his or her appointment as an SGE.

3. The relationship of the representational activities to the regular duties of the SGE: When the meeting does not involve the Division or Office for which the SGE works, then CDER is more likely to allow representational activities.

- CDER retains the discretion to place limits on the representational activities of its SGEs. For example: 1) CDER could limit the representational activities of an SGE to just discussing the trial in which he or she served as principal investigator, or 2) CDER may limit the SGE to speaking only about the personal work of the SGE.

- The SGE may not represent a sponsor in any meeting with the FDA without written confirmation from the Advisors and Consultants Staff of CDER approval. Advisory committee members are further restricted from representing sponsors in any capacity before their own advisory committee without written permission from the Center Director or Deputy Center Director (Review Management).

RESPONSIBILITIES AND PROCEDURES

- **The SGE will:**

1. notify the Advisors and Consultants Staff (ACS) at least two weeks prior to the meeting before agreeing to represent a sponsor in any meeting with the FDA;

2. provide a brief description of the present and past relationship to the sponsor and the application under consideration. This may be done in writing or by facsimile;

3. recuse himself or herself from any meeting with the FDA if he or she has worked as a SGE for more than 60 days out of previous consecutive 365 days or has ever worked on the particular matter for the FDA.

- **The ACS will:**

1. notify the appropriate CDER division and office of the SGE's participation;

2. if the division and office and the ACS disagree on whether it is appropriate for the SGE to attend a meeting, the matter will be forwarded to the Deputy Center Director (Review Management) for resolution;

3. inform the SGE of the decision in writing.

EFFECTIVE DATE

This MAPP is effective upon date of publication.