OFFICE OF MANAGEMENT

Outside Activities

CONTENTS

PURPOSE

- This MAPP describes the policies regarding outside activities in the Center for Drug Evaluation and Research (CDER) and specifies the responsibilities and procedures for requesting and authorizing outside activities or employment.

BACKGROUND

- This MAPP applies to all regular CDER employees, all employees detailed to CDER, and PHS Commissioned Corps personnel assigned to CDER programs.

REFERENCES

- Request for Approval of Outside Activity (HHS-520) Form (dated 01/06) http://intranet.fda.gov/omp/ethics/forms.htm

- FDA Staff Manual Guide 1430.2, Authority to Approve Outside Activities, February 25, 2005 (http://intranet.fda.gov/omp/smg/smg-htm/1430_2.htm)

- FDA Staff Manual Guide 3118.1, Supplementary Procedures for Protection Against Conflicts of Interest, August 15, 2003 (http://intranet.fda.gov/omp/smg/smg-htm/3118_1.htm)

- U.S. Office of Government Ethics, Standards of Ethical Conduct for Employees of the Executive Branch, October 2002, 5 CFR part 2635 (http://www.usoge.gov/pages/laws_regs_fedreg_stats/oge_regs/5cfr2635.html)

- Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services, 5 CFR part 5501, Chapter XLV, February 3, 2005 (http://intranet.fda.gov/omp/ethics/default.htm) (click HHS Supplemental Standards)

- FDA Ethics Program (http://www.fda.gov/opacom/ethics/default.htm)
- DHHS Standards of Conduct (Interim Guidance), 45 CFR part 73 (http://www.fda.gov/opacom/ethics/hhssoc.html)
- Division of Management Services (CDER) Web site: http://cdernet/dms/OutsideActivities.htm
- FDA Policy on the Review and Clearance of Articles to be Published in Scientific or Professional Journals (http://intranet.nctr.fda.gov/documents/FDAPublicationPolicy.pdf)
- CDER Manual of Policies and Procedures 4510.2, Clearance of Speeches, Articles, and Other Communication Materials, January 26, 1999
- Collective Bargaining Agreement Between the NTEU and the FDA, Article 55, October 1, 1999
- Annual Report of Outside Activity (HHS-521) Form (dated 01/06) (http://intranet.fda.gov/omp/ethics/forms.htm)

DEFINITIONS

- **Consultative services:** The provision of personal services by an employee, including the rendering of advice or consultation, which requires advanced knowledge in a field of science or learning customarily acquired by a course of specialized instruction and study in an institution of higher education, hospital, or other similar facility.
- **Federal Liaison Representative:** An employee assigned by the Center Director or designee to participate in an organization as part of his or her official duty. Participation could include participating in committees, panels, workshops, task group meetings, or other professional activities. Participation does **not** include participating as a board member of an organization, because a Federal Liaison Representative should not be involved with the internal management of the organization.
- **Honorarium:** Payment of money or other things of value, whether made gratuitously or as a fee for an appearance, speech, or article unrelated to official duties. Does not include salary or compensation made for services rendered on a continuing basis, such as for teaching, or proceeds from the sale of a book or similar undertaking.
- **Official time:** Time for which an employee is paid a salary or similar payment from the Federal Government or that time during which an employee is expected to perform official duties.
- **Outside activity:** Any activity, compensated or not, initiated by an employee (not in response to official direction), during an employee's personal off-duty time, not using Agency resources and performed outside FDA premises, for which the FDA Conflict of Interest Regulations require advance administrative approval.

Outside activities requiring prior approval:

1. Professional or consultative services (including service as an expert witness).

2. Teaching, speaking, writing, or editing that relates to official duties, or would be undertaken as a result of an invitation by someone that is a prohibited source of the FDA (see definition of *prohibited source*, below).

3. Service to a non-Federal entity as an officer, director, or board member or as a member of a group, such as a planning commission, advisory council, editorial board, or scientific or technical advisory board or panel, that requires the provision of advice, counsel, or consultation.

4. Employment, including uncompensated employment, undertaken at the invitation of or performed for a prohibited source of the FDA.

   Notwithstanding the four criteria listed above, prior approval is not required for activities of a political, religious, social, fraternal, or recreational organization unless (1) the activity or position held in the organization requires the provision of professional services, or (2) the activity is performed for compensation other than the reimbursement of expenses.

- **Professional services:** The provision of personal services by an employee, including the rendering of advice or consultation, that involve the skills of profession.

- **Prohibited source:** Any source involved in the following activities:

  1. Seeking official action by the Agency

  2. Doing business or seeking to do business with the Agency

  3. Conducting activities regulated by the Agency

  4. Having interests that may be substantially affected by performance or nonperformance of the employee's official duties

  5. Conducting business or acting as an organization in which a majority of the members or employees are involved in activities 1-4 above.

POLICY

- Advance approval is required for outside activities listed above in the definition, paid or unpaid, unless specifically exempted from the advance approval requirement under this MAPP.

- Outside activities, although not an employee entitlement, will ordinarily be approved when they do not adversely affect performance of an employee's official duties, constitute a potential conflict of interest or appearance of a conflict of interest, or create an adverse effect on the image of FDA.

- The approval of outside activities will be effective for a period not to exceed 1 year from the date of approval. Employees are required to resubmit Form HHS-520 each year before the expiration date if the activity is to continue.

- **Outside activity requests will be approved or disapproved in approximately 6 weeks following receipt by the Office of Management, CDER**. This time frame may be extended if requests are incomplete, do not include enough information to determine that there is no conflict of interest, or require consultation with the Ethics attorney.

- Professional or Consultative Services

    1. Employees may not work, with or without compensation, for organizations, institutions, or state or local governments either directly related to the official duties of the employee or indirectly related to the official duties of the employee if the indirect relationship is significant enough to cause the existence of a conflict of interest or appearance of a conflict of interest.

    2. Employees may not work for compensation to help a person, institution, or government unit prepare, or aid in the preparation of, grant applications, contract proposals, and other materials designed to become the subject of dealings between the institutions or government units and the Federal Government.

- Holding Office in Professional Societies. Activity in professional associations is generally desirable from the point of view of the Department and the employee. Employees should avoid a conflict of interest or an appearance of a conflict of interest. Employees must not:

    1. Serve in capacities involving them as representatives of non-government organizations dealing with the government.

    2. Permit their names or government titles to be attached to documents when distribution of those documents would be likely to embarrass the Department.

- Writing, Editing, Teaching, Speaking. Disclaimers stating that the views expressed do not necessarily represent the views of the Agency must be used if:

    1. The employee identifies himself or herself by official title or affiliation with the Department; or

    2. The prominence of the employee or his or her position or other reason might lead the public to associate him or her with FDA even when no identification other than the employee's name is used.

- Honoraria. Receipt of honoraria is permissible for all employees provided that the activity is **not** related to official duties. There is no limit on the amount of an honorarium.

    Exceptions to the receipt of honoraria. Political appointees are subject to additional restrictions, Senate confirmed Presidential appointees are subject to the ban on outside earned income (Executive Order 12674), and non-career SES appointees are subject to an annually adjusted cap on outside earned income.

RESPONSIBILITIES AND PROCEDURES

The Employee will:

- Become familiar with and observe the rules set forth in the Standards of Ethical Conduct for Employees of the Executive Branch, the DHHS Standards of Conduct, and the FDA Conflict of Interest Regulations.

- Complete the Request for Approval of Outside Activity, HHS-520. All questions must be answered.

  For activities involving teaching, speaking, or writing, the employee must provide a syllabus, outline, summary, synopsis, draft, or similar description of the content and subject matter involved in the course, speech, or written product (*including, if available, a copy of the text of any speech*) and the proposed text of any disclaimer that indicates that the views expressed do not necessarily represent the views of the Agency or the United States.

  A copy of the employee's position description may be attached in lieu of providing a description of the principal duties and responsibilities of his or her current FDA position (Part III.1 of the form), unless there are significant duties or assignments that are not reflected in the position description.

  Attach to the Request for Approval letters of invitation, Web site information, and any other relevant documents to assist in the determination of approval or disapproval.

  Sign and date Part III.5, certifying that the notices in Part VIII of the request have been read and understood and that the statements made and information provided on the request are true, complete, and correct to the best of his or her knowledge.

- Ensure that the outside employment and activities do not interfere with performance of official duties or constitute a potential conflict of interest or an appearance of a conflict of interest.

- Obtain the immediate supervisor's comments, recommendation, signature, and date in Part IV.2 and 3 of the request.

- Forward the request to the program specialist or management officer.

- Verify final approval of the activity by receipt of the approved HHS-520 before beginning the activity.

- Complete the Annual Report of Outside Activity (HHS-521) for all approved outside activities even if not actually undertaken. Any outside activities that were undertaken without advance approval of the HHS-520 must be reported on the HHS-521.

The Immediate Supervisor will:

- Review the outside activity request, describe the extent to which the employee's official duties are related to the proposed activity in Part IV.2, make a recommendation, sign and date Part IV.3 of the request.

- Return the signed request to the requesting employee.

The Program Specialist/Management Officer will:

- Review the HHS-520 promptly for completeness, and ensure that adequate information is submitted for review and decision relative to approval.
- Obtain the division director's comments, signature, and date in Part IV.2 of the request.
- Obtain the office director's or staff director's signature and date in Part IV.2 of the request.
- Forward the HHS-520 to the Center's Outside Activity Coordinator to obtain concurrence or nonconcurrence by the Deputy Center Director and approval or disapproval by the Agency approving official.
- Maintain a file of employee's outside activities.

The Division Director will:

- Review the outside activity request, describe the extent to which the employee's official duties are related to the proposed activity, and sign and date Part IV.2 of the request.
- Return the signed request to the program specialist or management officer.

The Office Director/Staff Director (OCD) will:

- Review the outside activity request for content and possible conflict of interest.
- Sign and date Part IV.2.
- Return the request to the program specialist or management officer.

The Outside Activity Coordinator, Division of Management Services, OM, will:

- Review the outside activity request for completeness, content, and possible conflict of interest issues.
- Consult with the Agency's Ethics and Integrity Staff, when necessary, concerning any potential conflict of interest before forwarding the HHS-520 to the Deputy Center Director for concurrence or nonconcurrence.
- Forward the form HHS-520 to the Deputy Center Director for concurrence or nonconcurrence.

- After the Deputy Center Director has signed and returned the HHS-520, forward the original copy of the HHS-520 to the Ethics and Integrity Staff, HFA-320.

- Forward a copy of the approved or disapproved request to the program specialist or management officer for their records.

- Retain a file copy of all HHS-520s and accompanying memorandums for 6 years.

The Deputy Center Director will:

- Review the HHS-520, concur or nonconcur, explain the reason(s) for concurrence or nonconcurrence, and sign and date Part V of the request.

- Return the HHS-520 to the Center's Outside Activity Coordinator to forward to the Ethics and Integrity Staff for obtaining final approval by the Agency.

The Ethics and Integrity Staff will:

- Review the HHS-520 for completeness and any possible conflicts of interest.

- Complete Part VI of the request and forward the request to the approving official to complete Part VII.

- Once the HHS-520 is approved or denied by the Approving Official and returned to the Ethics and Integrity Staff, forward a copy of the completed request to the requesting employee, the employee's supervisor, and the Center's Outside Activity Coordinator.

- Maintain the original HHS-520s, accompanying memorandums, and all attachments for 6 years.

AUTHORITY

- The Director, Center for Drug Evaluation and Research, has the authority to delegate final Center concurrence or nonconcurrence to the Deputy Center Director.

EFFECTIVE DATE

This MAPP is effective upon date of publication.