

**MANAGEMENT**

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**OUTSIDE ACTIVITIES**

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**Attachment A: Form HHS-520 - Request for Approval of Outside Activity**

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**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/employment.

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**APPLICABILITY**

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

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**REFERENCES**

- FDA Staff Manual Guide 1430.2, *Authority to Approve Outside Activities*, July 27, 1995.
- FDA Staff Manual Guide 3118.1, *Supplementary Procedures for Protection Against Conflicts of Interest*, December 28, 1987.
- OGE Standards of Ethical Conduct for Employees of the Executive Branch, August 1992, 5 CFR Part 2635.

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- DHHS Standards of Conduct, 45 CFR Part 73, Subpart G.
  - FDA Conflict of Interest Regulations, 45 CFR Part 73a., Subpart D.
  - CDER Manual of Policies and Procedures 4510.2, *Clearance of Speeches, Articles, and Other Communication Materials*, November 7, 1995.
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## DEFINITIONS

- **Approving Official.** The Executive Officer/Director, Office of Management, is the person responsible for final approval/disapproval of outside activity requests.
- **Federal Liaison Representative.** An employee designated by the Center Director or designee to participate in an organization as part of his/her official duty. Participation could include participating in committee, panel, workshop, or task group meetings and other professional activities. Participation does not include participating as a board member of the 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 as 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 utilizing agency resources and performed outside FDA premises, for which the FDA Conflict of Interest Regulations require advance administrative approval.

### **Outside activities include, but are not limited to:**

1. Employment outside the agency (whether compensated or not).

2. Professional or consultative services.
3. Holding office in a professional society or a scientific organization.
4. Writing, editing, teaching, speaking.

**Outside activities do not include:**

1. Membership or office holding in charitable, religious, social, fraternal, recreational, public service, civic, or similar non-business, non-governmental organizations.
2. Membership in professional organizations.
3. Performance of duties in the Armed Forces Reserve or National Guard.
4. Attendance and participation at meetings and conferences that are covered by Agency travel regulations and by guidelines established by individual Agency components.
5. Federal Liaison Representative of the Center or Agency.
6. Approved Professional Development Activities.

● **Professional or Consultative Services:**

1. For the purposes of this section, “professional or consultative work” is performance of work requiring knowledge of an advanced type in a field of science or learning customarily acquired by a course of specialized instruction and study in an institution of higher education, or hospital which requires the exercise of judgment and discretion in its performance and is primarily intellectual in nature as opposed to manual, mechanical or physical work.
2. Membership on a Board of Directors, Board of Regents, Board of Trustees, Planning Commission, Advisory Council or Committee, or on any similar body that provides advice, counsel, or consultation, shall be considered outside consultative services for which advance administrative approval is required.

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**POLICY**

- Advance approval is required for all outside activities, paid or unpaid, unless this Guide specifically exempts the outside activities from the advance approval requirement.
- 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.
- Approving Officials may not approve their own requests or requests made by their superiors.
- Professional or Consultative Services:
  1. Employees may not work, with or without compensation, for organizations, institutions, or state or local governments with which the official duties of the employee are directly related, or indirectly if the indirect relationship is significant enough to cause the existence of, 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 that are 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 in dealing with the government.
  2. Permit their names or government title to be attached to documents the distribution of which 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/herself by official title or affiliation with the Department; or
  2. The prominence of the employee or his/her position or other reason might lead the public to associate him/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 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.

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## RESPONSIBILITIES AND PROCEDURES

### Employee

- Becomes 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.
- Completes block 1 through block 16 on the “Request for Approval of Outside Activity” - Form HHS-520 (see Attachment A). Original signature must appear in block 14. Special attention should be given to Item 7 as follows:

Specify the "Nature of Activity," such as: professional/scientific or consultative services, holding office in professional societies, or outside employment. Give a brief description of specific duties or services to be performed. When possible, specify the scheduled days of the week and hours of the day that the proposed activity will be performed.
- Assures 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.
- Forwards the HHS-520 at least one month before the start date of the activity to the immediate supervisor for signature in block 17.

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

#### **The Immediate Supervisor**

- Reviews outside activity requests and recommends approval or disapproval in block 17. Comments, if necessary, can be made on back of form or on separate sheet and attached to the request.

If Offices want higher officials to also clear the form, these officials should initial in the margin.

- Forwards the HHS-520 to Management Officer or Program Specialist for further processing.

#### **The Management Officer or Program Specialist will:**

- Reviews the HHS-520 promptly for completeness and ensures that adequate information is submitted for review and decision relative to approval.
- Initials the HHS-520 in margin of block 17 after review.
- Forwards HHS-520 to the Administrative Management Team, HFD-61.
- Informs employee and employee's immediate supervisor, by signed copy of HHS-520, of final approval or disapproval.
- Maintains a file of employees' outside activities.

#### **The Administrative Management Team**

- Consults with the Agency's Division of Ethics and Program Integrity (DEPI), HFA-25, when necessary, concerning any potential conflict of interest prior to forwarding the HHS-520 to Approving Official, HFD-10, for final approval or disapproval.
- Initials bottom right of HHS-520 after review.
- Prepares a memorandum for Approving Official's signature stating the conditions or reasons for approval or disapproval of the activity.

- Forwards HHS-520 and accompanying memorandum to Approving Official for final signature in block 18.
- After Approving Official has signed and returned the HHS-520, forwards the original copy of approved HHS-520 and a copy of signed memorandum to Division of Ethics and Program Integrity, HFA-25.

Note: Disapproved outside activity requests (HHS-520) with accompanying memoranda are not sent forward to the Division of Ethics and Program Integrity. They are returned to Management Officer or Program Specialist who retains a copy for the file and returns the disapproved form to the employee and a copy to the supervisor.

- Returns three copies of the approved HHS-520, with original memorandum, to employee's Management Officer or Program Specialist, subsequent to final approval or disapproval of activity.
- Retains a file copy of HHS-520 and accompanying memorandum for three years.

#### **The Approving Official**

- Approves or disapproves all outside activity requests in block 18. Approving official may not approve either his/her own request or requests made by superiors.
  - Signs accompanying memorandum.
  - Returns HHS-520 and signed memorandum to Administrative Management Team, HFD-61, for final processing.
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#### **EFFECTIVE DATE**

This MAPP is effective upon date of publication.

Attachment A

**Form HHS-520**  
**Request for Approval of Outside Activity**

REFER TO THE HARD COPY OF THE MAPP FOR A COPY OF THIS FORM.