

**FDA Staff Manual Guides, Volume II – Delegations of Authority**

**Regulatory – Personnel**

**Outside Activities**

Effective Date: 25 April 2022

**1. Authority Delegated and To Whom Delegated.**

A. The officials listed below are authorized to approve, or recommend disapproval of, a Request for Approval of Outside Activity (HHS Form 520) as delegated to the Heads of HHS Operating Divisions in the HHS Special Counsel for Ethics memorandum of 30 March 1992; to PHS Agency Heads in the Deputy Assistant Secretary for Health Management Operations memorandum of 12 June 1992; and to the FDA Deputy Commissioner for Operations in the HHS Associate General Counsel for Ethics memorandum of 23 August 2016:

- (1) Office of Operations (OO)/Office of Ethics and Integrity (OEI) Director or their designee.
- (2) Center for Biologics Evaluation and Research (CBER)/Office of Management (OM) Associate Director for Management.
- (3) Center for Drug Evaluation and Research (CDER)/Office of Management (OM) Associate Director for Management
- (4) Center for Devices and Radiological Health (CDRH)/Office of Management (OM) Associate Director for Management.
- (5) Center for Food Safety and Applied Nutrition (CFSAN)/Office of Management (OM) Associate Director for Management.
- (6) Center for Tobacco Products (CTP)/Office of Management (OM) Associate Director for Management.
- (7) Center for Veterinary Medicine (CVM)/Office of Management (OM) Associate Director for Management.
- (8) Office of Regulatory Affairs (ORA)/Office of Management (OM) Assistant Commissioner for Regulatory Management Operations.
- (9) Office of the Chief Scientist (OCS)/National Center for Toxicological Research (NCTR)/Office of Management (OM) Associate Director for Management.
- (10) OO/Office of Enterprise Management Services (OEMS) Associate Director for Management for the Office of the Commissioner (OC) and non-Center organizations that report directly to OC.

## 2. Limitations.

- A. The authority to approve outside activities for Senior Executive Service (SES) or SES equivalent positions (employee serving under Title 38 or 42 appointment authority), or those acting or assuming the duties of an SES or SES-equivalent position for more than 30 days, is reserved for the OEI Director (or designee) and cannot be redelegated.
- B. The authority to deny an HHS 520 is reserved to the OO/OEI Director or designee.
- C. Approving officials are required to follow the OEI Standard Operating Procedures and use the standard OEI approved guidance including conditions of approval provided by OEI.
- D. Approving officials must provide regular updates to OEI, according to the schedule specified by OEI, on the HHS Form 520s approved by their organization.

## 3. Redelegation.

- A. The positions identified in Sections 1.A.(2) – (10) may redelegate the authority to approve an HHS 520 to other senior management officials in their respective organizations at a high enough level to be consistent with good management practices and with written concurrence of the OEI Director. The positions identified in Sections 1.A.(2) – (10) may restrict the degree of redelegation or identify specific positions for the approval of certain activities such as one-time speaking or writing engagements.
- B. Delegates must be certified as knowledgeable about the legal, regulatory, and policy requirements regarding the subject authorities and they are subject to compliance audits.
- C. Any redelegation must be in writing and specify the nature and extent of the authority redelegated.
- D. A copy of the redelegation must be furnished to the Principal Delegation Control Officer.

## 4. Effective Date.

The Deputy Commissioner for Operations & Chief Operating Officer approved this delegation, via memorandum, on 25 April 2022.

| Status  | Date Approved | Location of Change History | Contact              | Approving Official  |
|---------|---------------|----------------------------|----------------------|---|
| Initial | 06/04/2010    | N/A                        | OC/<br>OA/<br>OM/OMP | Kimberly Holden<br>Associate Commissioner<br>for Management |

| <b>Status</b> | <b>Date Approved</b> | <b>Location of Change History</b> | <b>Contact</b> | <b>Approving Official</b>   |
|---------------|----------------------|-----------------------------------|----------------|---|
| Revision      | 04/25/2022           | N/A                               | OO/<br>OEI     | James M. Sigg<br>Deputy Commissioner<br>for Operations<br>& Chief Operating Officer |