

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - GENERAL REDELEGATIONS OF AUTHORITY

AUTHORITY TO SELECT TEMPORARY VOTING MEMBERS FOR ADVISORY COMMITTEES AND AUTHORITY TO SIGN CONFLICT OF INTEREST WAIVERS

Effective Date: 06/04/2010

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

- A. Each Center Director is authorized to select members of scientific and technical FDA advisory committees under that center's management, and special government employees and regular government employees under that center's management, to serve temporarily as members on another advisory committee under that center's management when expertise is required that is not available among current voting standing members of a committee or to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking.

When additional members are added to a committee to provide needed expertise not available among current voting standing members of a committee, a quorum will be based on the total of regular and added voting members.

Authority to select temporary voting members to advisory committees, if such members are serving on an advisory committee managed by another center or are otherwise under another center's management, has not been redelegated. This authority will continue to be exercised by the Commissioner of Food and Drugs (the Commissioner), the Associate Commissioner for Special Medical Programs, Office of the Commissioner, or the Assistant Commissioner for Special Medical Programs, Office of the Commissioner.

- B. The Associate Commissioner for Special Medical Programs and the Assistant Commissioner for Special Medical Programs are authorized to sign conflict of interest waivers in accordance with 21 U.S.C. 379d-1 and 18 U.S.C. 208(b)(1).208(b)(3), as amended, for special Government employees and regular government employees serving on advisory committees.

2. REDELEGATION.

These officials may not further redelegate this authority.

3. EFFECTIVE DATE.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on June 4, 2010.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	06/04/2010	N/a	OC/OA/ OM/OEO	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs