

FDA Staff Manual Guides, Volume II – Delegations of Authority

Administrative – Personnel

Senior Biomedical Research and Biomedical Product Assessment Service

Effective Date: 4 March 2022

1. Authority Delegated and to Whom Delegated.

A. The officials listed below are authorized to recommend or nominate individuals for initial appointments, conversions, details or reassignments for personnel serving in Senior Biomedical Research and Biomedical Product Assessment Service (SBRBPAS) positions per HHS Instruction 42-3, Senior Biomedical Research and Biomedical Product Assessment Service, as modified on 9 July 2021 to reflect section 3071 of the 21st Century CURES Act of 13 December 2016 (Public Law 114-255) which amended section 228 of the Public Health Service Act (42 U.S.C. 237):

- (1) Center for Biologics Evaluation and Research (CBER) Director and Deputy Director or their designee.
- (2) Center for Drug Evaluation and Research (CDER) Director and Deputy Directors or their designee.
- (3) Center for Devices and Radiological Health (CDRH) Director, Deputy Center Director for Science, and Deputy Center Director for Policy or their designee.
- (4) Center for Food Safety and Applied Nutrition (CFSAN) Director and Deputy Directors or their designee.
- (5) Center for Tobacco Products (CTP) Director and Deputy Director or their designee.
- (6) Center for Veterinary Medicine (CVM) Director and Deputy Director or their designee.
- (7) Office of Regulatory Affairs (ORA) Associate Commissioner for Regulatory Affairs and Deputy Associate Commissioner for Regulatory Affairs or their designee.
- (8) Office of Clinical Policy and Programs (OCP) Director or their designee.
- (9) Office of the Chief Scientist (OCS) Chief Scientist or their designee.
- (10) OCS/National Center for Toxicological Research (NCTR) Director and Deputy Director or their designee.
- (11) Office of Digital Transformation (ODT) Chief Information Officer or their designee.
- (12) Office of External Affairs (OEA) Director or their designee.

- (13) Office of the Executive Secretariat (OES) Director or their designee.
 - (14) Office of Food Policy and Response (OFPR) Deputy Commissioner for Food Policy and Response or their designee.
 - (15) Office of Minority Health and Health Equity (OMHHE) Director or their designee.
 - (16) Office of Operations (OO) Deputy Commissioner for Operations & Chief Operating Officer or their designee.
 - (17) Office of Policy, Legislation, and International Affairs (OPLIA) Deputy Commissioner for Policy, Legislation, and International Affairs or their designee.
 - (18) Office of Women's Health (OWH) Associate Commissioner for Women's Health or their designee.
 - (19) Oncology Center of Excellence (OCE) Director or their designee.
 - (20) SBRBPAS Review Board Chairperson or their designee.
 - (21) Executive Resources Board Chairperson or their designee.
- B. The officials listed below are authorized to determine the qualifications of candidates for SBRBPAS positions per HHS Instruction 42-3-40. D. 4. and 42-3-70. D. 2.:
- (1) OO/Office of Talent Solutions (OTS) SBRBPAS Program Staff.
 - (2) SBRBPAS Review Board Chairperson or their designee.
 - (3) Executive Resources Board Chairperson or their designee.
- C. The officials listed below are authorized to approve initial appointments, conversions, details, and reassignments for personnel serving in SBRBPAS positions per HHS Instruction 42-3-40. C. 2. ii.:
- (1) OO Deputy Commissioner for Operations & Chief Operating Officer.
 - (2) OO/OTS Chief Talent Officer.
- D. The officials listed below are authorized to recommend initial pay and pay adjustments up to the \$275,000 pay cap for personnel serving in SBRBPAS positions per HHS Instruction 42-3-80. B. 1. and 42-3-80 B. 3.:
- (1) CBER Director and Deputy Director or their designee.
 - (2) CDER Director and Deputy Directors or their designee.
 - (3) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy or their designee.
 - (4) CFSAN Director and Deputy Directors or their designee.
 - (5) CTP Director and Deputy Director or their designee.
 - (6) CVM Director and Deputy Director or their designee.

- (7) ORA Associate Commissioner for Regulatory Affairs and Deputy Associate Commissioner for Regulatory Affairs or their designee.
 - (8) OCPP Director or their designee.
 - (9) OCS Chief Scientist or their designee.
 - (10) OCS/NCTR Director and Deputy Director or their designee.
 - (11) ODT Chief Information Officer or their designee.
 - (12) OEA Director or their designee.
 - (13) OES Director or their designee.
 - (14) OFPR Deputy Commissioner for Food Policy and Response or their designee.
 - (15) OMHHE Director or their designee.
 - (16) OO Deputy Commissioner for Operations & Chief Operating Officer or their designee.
 - (17) OPLIA Deputy Commissioner for Policy, Legislation, and International Affairs or their designee.
 - (18) OWH Associate Commissioner for Women's Health or their designee.
 - (19) OCE Director or their designee.
 - (20) SBRBPAS Review Board Chairperson or their designee.
 - (21) Executive Resources Board Chairperson or their designee.
- E. The officials listed below are authorized to approve initial pay and pay adjustments up to the \$275,000 pay cap for personnel serving in SBRBPAS positions per HHS Instruction 42-3-40. C. 2. iii.:
- (1) OO Deputy Commissioner for Operations & Chief Operating Officer.
 - (2) OO/OTS Chief Talent Officer.
- F. The officials listed below are authorized to recommend discipline or recommend removal for cause for personnel serving in SBRBPAS positions per HHS Instruction 42-3-40. C. 2. v.:
- (1) CBER Director and Deputy Director or their designee.
 - (2) CDER Director and Deputy Directors or their designee.
 - (3) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy or their designee.
 - (4) CFSAN Director and Deputy Directors or their designee.
 - (5) CTP Director and Deputy Director or their designee.
 - (6) CVM Director and Deputy Director or their designee.
 - (7) ORA Associate Commissioner for Regulatory Affairs and Deputy Associate Commissioner for Regulatory Affairs or their designee.

- (8) OCPP Director or their designee.
 - (9) OCS Chief Scientist or their designee.
 - (10) OCS/NCTR Director and Deputy Director or their designee.
 - (11) ODT Chief Information Officer or their designee.
 - (12) OEA Director or their designee.
 - (13) OES Director or their designee.
 - (14) OFPR Deputy Commissioner for Food Policy and Response or their designee.
 - (15) OMHHE Director or their designee.
 - (16) OO Deputy Commissioner for Operations & Chief Operating Officer or their designee.
 - (17) OPLIA Deputy Commissioner for Policy, Legislation, and International Affairs or their designee.
 - (18) OWH Associate Commissioner for Women's Health or their designee.
 - (19) OCE Director or their designee.
- G. The officials listed below are authorized to approve disciplinary or approve removal for cause for personnel serving in SBRBPAS positions per HHS Instruction 42-3-40. C. 2. v. and 42-3-100 A.:
- (1) Commissioner of Food and Drugs.
 - (2) OO Deputy Commissioner for Operations & Chief Operating Officer.
 - (3) OO/Office of Human Capital Management (OHCM) Director.
- H. The officials listed below are authorized to approve the appointment of a former SBRBPAS member who was removed without cause to a position covered by Title 5 per HHS Instruction 42-3-40. C.2.vi.:
- (1) Commissioner of Food and Drugs.
 - (2) OO Deputy Commissioner for Operations & Chief Operating Officer.
 - (3) OO/OTS Chief Talent Officer.
- I. The official listed below is authorized to establish a SBRBPAS peer review committee and to select a Chairperson per HHS Instruction 42-3-40. D. 3.:
- (1) Commissioner of Food and Drugs.

2. Limitations

- A. HHS Operating Divisions are authorized to set annual pay, including pay increases, for SBRBPAS members up to \$275,000 per annum. Annual pay exceeding this amount must be approved in writing by the Secretary or designee prior to its effective date per HHS Instruction 42-3-80. B.

3. Redelegations.

- A. Designees must be certified as knowledgeable about the legal, regulatory, and policy requirements regarding the subject authorities and they are subject to compliance audits.
- B. Designees must be appointed in writing.
- C. A copy of the designee appointment must be furnished to the OO/OHCM Director, the OO/OTS Chief Talent Officer, and the Principal Delegation Control Officer.

4. Effective Date.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on 4 March 2022.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	03/04/2022	N/A	OO/ OTS/ PAS	Robert M. Califf, M.D., MAcc Commissioner of Food and Drugs