**SMG 1410.21**

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

**Regulatory – General Redelegations of Authority**

# General Redelegations of Authority from the Commissioner to Other Officers of the Food and Drug Administration

Effective Date: 17 February 2022
Changed: 26 January 2024

## 1. Authority Delegated and To Whom Delegated.

A. Final authority of the Commissioner of Food and Drugs (Commissioner) is redelegated as referenced in the Food and Drug Administration (FDA) Staff Manual Guide (SMG) 1400 series. The Commissioner may continue to exercise all delegated authority referenced in these SMGs.

B. The officials listed below are authorized to perform all delegable functions of the Commissioner. These officials may not further redelegate this authority, or any part of this authority, except as elsewhere specified:

(1) Principal Deputy Commissioner, Office of the Commissioner (OC).

(2) Chief of Staff, OC.

(3) Deputy Commissioner for Policy, Legislation, and International Affairs, Office of Policy, Legislation, and Analysis (OPLIA).

(4) Deputy Commissioner for Food Policy and Response, Office of Food Policy and Response, Office of Food Policy and Response (OFPR).

(5) Chief Scientist, Office of Chief Scientist (OCS).

(6) Deputy Commissioner for Operations & Chief Operating Officer, Office of Operations (OO).

(7) Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs (ORA).

C. The Federal Vacancies Reform Act of 1998 (Vacancies Reform Act) applies if the Commissioner dies, resigns, or is otherwise unable to perform the functions and duties of the Office of the Commissioner.

(1) When the Vacancies Reform Act applies, the Principal Deputy Commissioner shall be designated as “first assistant” and shall act as Commissioner unless the Principal Deputy Commissioner does not meet the requirements of the Vacancies Reform Act or the President has directed someone else to act as Commissioner pursuant to the Vacancies Reform Act.

(2) During an absence of the Commissioner that does not trigger the requirements of the Vacancies Reform Act, the first official in the following order who is available, or the official in the following list who has been designated by the Commissioner to serve in an acting capacity, shall lead the FDA (specific delegations provided below do not limit the general delegations provided by this section to the designated officials who are authorized to perform all of the delegable functions of the Commissioner):

a. Principal Deputy Commissioner, OC.

b. Chief of Staff, OC.

c. Deputy Commissioner for Policy, Legislation, and International Affairs, OPLIA.

d. Deputy Commissioner for Food Policy and Response, OFPR.

e. Chief Scientist, OCS.

f. Deputy Commissioner for Operations & Chief Operating Officer, OO.

g. Associate Commissioner for Regulatory Affairs, ORA.

D. Authority delegated to a position by title may be exercised by a person officially designated to serve in that position in an acting capacity or on a temporary basis, unless prohibited by a restriction in the document designating them as "acting" or unless not legally permissible.

E. The officials listed below are authorized to perform all the functions of the officials under them in their respective organizations and they may not further redelegate this authority:

(1) Principal Deputy Commissioner, OC.

(2) Deputy Commissioner for Policy, Legislation, and International Affairs, OPLIA.

(3) Deputy Commissioner for Food Policy and Response, OFPR.

(4) Chief Scientist, OCS.

(5) Deputy Commissioner for Operations & Chief Operating Officer, OO.

(6) Associate Commissioner for Regulatory Affairs, ORA.

(7) Chief Counsel, Office of the Chief Counsel (OCC).

F. The Chief Scientist, OCS, and the Director of the Advisory Committee Oversight and Management Staff, OCS/ACOMS, are authorized:

(1) To make determinations that advisory committee meetings are concerned with matters listed in 5 U.S.C. 552(b) and therefore may be closed to the public in accordance with 21 CFR 14.27.

(2) To perform other associated advisory committee functions, e.g., establishing technical and scientific review groups (advisory committees);

appointing and paying members; approving waivers to appoint members to established advisory committees; renewing and rechartering of established advisory committees; amending charters of established advisory committees; and terminating established advisory committees.

(3) To approve conflict of interest waivers for Special Government Employees (SGEs) and regular government employees serving on advisory committees in accordance with 21 U.S.C. 379d-1 and 18 U.S.C. 208(b)(1) and 208(b)(3), as amended.

(4) To select temporary members for advisory committees if such voting members are serving on an advisory committee managed by a center or office other than OCS.

G. The Director, Office of Clinical Policy and Programs (OCPP)/Office of Combination Products (OCP) is authorized:

(1) Under section 503(g)(8)(E)(ii) of the Federal, Food, Drug and Cosmetic Act (FFDCA), as added by section 204 of the Medical Device User Fee Modernization Act of 2002 (MDUFMA), with respect to combination products the following: "During the review process, any dispute regarding the substance of premarket review may be presented to the Commissioner of Food and Drugs after first being considered by the center with primary jurisdiction of the premarket review, under the scientific dispute resolution procedures for such center. The Commissioner shall consult with the OCPP/OCP Director in resolving the substantive dispute."

H. The Deputy Commissioner for Policy, Legislation, and International Affairs, OPLIA; the Principal Associate Commissioner for Policy, Office of Policy (OP), OPLIA; the Associate Commissioner for Policy, OP, OPLIA; and the Director, Office of Global Policy and Strategy (OGPS), OPLIA are authorize:

(1) To perform any of the functions of the Commissioner with respect to the issuance of Federal Register (FR) notices and proposed and final regulations of the FDA. This authority may not be further redelegated.

(2) To issue responses to the following matters under 21 CFR part 10 as follows and these officials may not further redelegate this authority:

a. Requests for waiver, suspension, or modification of procedural requirements under 21 CFR 10.19.

b. Citizen petitions under 21 CFR 10.30.

c. Petitions for reconsideration under 21 CFR 10.33.

d. Petitions for stay under 21 CFR 10.35.

e. Requests for advisory opinions under 21 CFR 10.85.

(3) With respect to any matter delegated to the Deputy Commissioner for Policy, Legislation, and International Affairs, the Principal Associate Commissioner for Policy, and the Associate Commissioner for Policy,

under this paragraph, the Deputy Commissioner for Policy, Legislation, and International Affairs, the Principal Associate Commissioner for Policy, and the Associate Commissioner for Policy, are authorized to perform the functions of the Commissioner under 21 CFR 10.40, 10.45, 10.50, 10.55, 10.60, 10.65, 10.80, 10.90, and 10.95 and of a Deputy Commissioner under 21 CFR10.206(g) and (h). These authorities may not be further redelegated.

(4) To certify that a proposed or final rule, if issued, will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 605(b)). The Deputy Commissioner for Policy, Legislation, and International Affairs, OPLIA; the Principal Associate Commissioner for Policy, OP, OPLIA, and the Associate Commissioner for Policy, OP, OPLIA, may further redelegate this authority.

(5) To make all determinations and findings under 21 CFR part 15, and to waive, suspend, or modify any procedural requirements related to 21 CFR part 15, section 10.19.

I. The Center for Drug Evaluation and Research (CDER)/Office of Regulatory Policy (ORP) Director and Deputy Director are authorized:

(1) To waive or reduce prescription drug user fees in situations where the CDER/ORP Director and Deputy Director find that such a waiver or reduction:

a. is necessary to protect public health under section 736(d)(1)(A) of the FFDCA (21 U.S.C. 379h(d)(1)(A)), as amended;

b. is necessary because the fee would present a significant barrier to innovation under section 736(d)(1)(B) of the FFDCA (21 U.S.C. 379h(d)(1)(a)), as amended; or

c. is appropriate under section 736(d)(1)(C) of the FFDCA (21 U.S.C. 379h(d)(1)(D)), as amended because the applicant involved is a small business submitting its first human drug application.

These authorities may not be further redelegated.

(2) To act upon requests for consideration of any user fee decisions under section 736 of the FFDCA (21 U.S.C. 379h), other than decisions on fee-exceed-the cost waiver requests, made by such officers and the former Deputy User Fee Waiver Officer prior to July 1, 1999 or the Associate Director for Policy prior to 2020. These authorities may not be further redelegated.

J. The Center for Veterinary Medicine (CVM)/Office of the Center Director (OCD)/ Policy and Regulations Staff (PRS) Director, is authorized:

(1) To waive or reduce animal drug user fees in situations where the CVM/OCD/PRS Director finds that such a waiver or reduction:

a. is necessary because the fee would present a significant barrier to innovation under section 740(d)(1)(A) of the FFDCA (21 U.S.C. 379j-12(d)(1)(A)), as amended;

b. is necessary because the animal drug application or supplemental animal drug application is intended solely to provide for use of the animal drug in medicated feeds under section 740(d)(1)(C) of the FFDCA (21 U.S.C. 379j-12(d)(1)(C)), as amended;

c. is necessary because the animal drug application or supplemental animal drug application is intended solely to provide for a minor use or minor species indication under section 740(d)(1)(D) of the FFDCA (21 U.S.C. 379j-12(d)(1)(D)), as amended; or

d. is appropriate under section 740(d)(1)(E) of the FFDCA (21 U.S.C. 379j-12(d)(1)(E)), as amended because the applicant involved is a small business submitting its first animal drug application.

This authority may not be redelegated.

(2) To waive or reduce generic animal drug user fees in situations where the CVM/OCD/PRS Director finds that such a waiver or reduction is necessary because a generic new animal drug is intended solely to provide for a minor use or minor species indication under section 741(d)(1) of the FFDCA (21 U.S.C. 379j-21(d)(1)), as amended.

(3) Under any of the above cited provisions of section 740 and 741 of the FFDCA, to act upon requests for reconsideration of decisions made. This authority may not be redelegated

K. The CVM/OCD Deputy Directors are authorized to act upon requests for reconsideration of decisions made under any provision of section 740 and 741 of the FFDCA, except for those decisions that pertain to fee-exceed-the cost waiver requests. This authority may not be further redelegated.

L. The Deputy Commissioner for Operations & Chief Operating Officer, OO, is authorized to perform the functions of the Commissioner under:

(1) Section 736(d)(1)(c) of the FFDCA (21 U.S.C. 379h (d)(1)(C)), as amended, to waive or reduce prescription drug user fees in situations where the Deputy Commissioner for Operations & Chief Operating Officer finds that "the fees will exceed the anticipated present and future costs." The Deputy Commissioner for Operations may further redelegate the authority in this paragraph in whole or in part to the OO/Office of Finance, Budget, Acquisitions, and Planning (OFBAP) Chief Financial Officer.

(2) Section 740(d)(1)(B) of the FFDCA, to waive or reduce animal drug user fees, for waiver or reduction requests made on the basis that the fees assessed exceed the costs to FDA for reviewing applications. The Deputy Commissioner for Operations & Chief Operating Officer may further redelegate the authority in this paragraph in whole or in part to the Chief Financial Officer.

(3) Section 736(c)(4) of the FFDCA, as amended by the Prescription Drug User Fee Act Amendments of 2002, to establish application and product fees under section 736(a), based on the revenue amounts established under section 736(b) and the adjustments under 736(c). The Deputy Commissioner for Operations & Chief Operating Officer may further redelegate the authority in this paragraph in whole or in part to the Chief Financial Officer.

(4) Section 738 of the FFDCA, as added by the MDUFMA, to adjust and set fee rates for medical device applications each year. The Deputy Commissioner for Operations & Chief Operating Officer may further redelegate the authority in this paragraph in whole or in part to the Chief Financial Officer.

(5) Section 740(c) of the FFDCA, to adjust and set new and supplemental animal drug application fees, animal drug sponsor fees, animal drug product fees, and animal drug establishment fees. The Deputy Commissioner for Operations & Chief Operating Officer may further redelegate the authority in this paragraph in whole or in part to the Chief Financial Officer.

(6) Section 741(c) of the FFDCA, to adjust and set abbreviated application fees, generic new animal drug sponsor fees, and generic new animal drug product fees. The Deputy Commissioner for Operations & Chief Operating Officer may further redelegate the authority in this paragraph in whole or in part to the Chief Financial Officer.

(7) Section 919(b)(6)) of the FFDCA (21 U.S.C. 387s(c)(6)), to notify each manufacturer and importer of tobacco products subject to this section of the amount of the quarterly assessment due for such products. The Deputy Commissioner for Operations & Chief Operating Officer may further redelegate the authority in this paragraph in whole or in part to the Chief Financial Officer.

(8) Under any fees-exceed-cost user fee waiver or reduction sections of the FFDCA noted above, act upon requests for reconsideration of decisions made by such officers. This authority may not be redelegated.

M. The Chief Scientist, OCS, is designated as the User Fee Appeals Officer. The User Fee Appeals Officer is authorized to hear and decide user fee waiver appeals. The decision of the User Fee Appeals Officer will constitute final FDA action on such matters. The User Fee Appeals Officer may not further redelegate this authority.

N. The Deputy Commissioner for Operations & Chief Operating Officer, OO, is authorized to perform all of the administrative authorities (i.e., financial, personnel, facilities management, property management, etc.) of the Commissioner. These authorities may be further redelegated except when specifically prohibited.

O. The officials listed below are authorized to grant or deny a request to issue an emergency use authorization (EUA) under section 564 of the FFDCA, and to consult under section 564(c) of the FFDCA, requiring “consultation with the Director of the National Institutes of Health and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the circumstances of the emergency involved)” prior to issuing an EUA:

   (1) Center for Biologics Evaluation and Research (CBER) Director and Deputy Director.

   (2) Center for Drug Evaluation and Research (CDER) Director and Deputy Directors.

   (3) Center for Devices and Radiological Health (CDRH) Director, Deputy Center Director for Science, and Deputy Center Director for Policy.

   (4) Center for Veterinary Medicine (CVM) Director.

   (5) OCS Chief Scientist.

P. The officials listed below are authorized to issue the final decision regarding the disqualification of a clinical investigator, i.e., the investigator's eligibility to receive investigational articles under 21 CFR 312.70(b), 511.1(c)(2), or 812.119(b):

   (1) OCS Chief Scientist.

   (2) OCPP Associate Commissioner for Clinical Policy and Programs.

Q. The officials listed below are authorized to sign a consent agreement between the FDA and a clinical investigator regarding the disqualification of the clinical investigator, resulting in the clinical investigator’s ineligibility to receive investigational articles under 21 CFR 312.70(b), 511.1(c)(2), or 812.119(b) and containing a binding provision that disqualification pursuant to the consent agreement has the same legal effect as being disqualified pursuant to the relevant regulation after a Part 16 Hearing:

   (1) CBER Director.

   (2) CBER/Office of Compliance and Biologics Quality (OCBQ) Director and Deputy Director.

   (3) CDER Director.

   (4) CDER/Office of Compliance (OC) Director and Deputy Director.

   (5) CDER/OC/Office of Scientific Investigations (OSI) Director and Deputy Director.

   (6) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.

   (7) CDRH/Office of Product Evaluation and Quality (OPEQ) Director; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy and Guidance; and Chief Medical & Science Officer.

(8) CDRH/OPEQ/Office of Clinical Evidence and Analysis (OCEA) Director.

(9) CDRH/OPEQ/Office of Regulatory Programs (ORP) Director.

(10) CVM Director.

(11) CVM/Office of Surveillance and Compliance (OSC) Director and Deputy Director.

(12) CVM/OSC/Division of Compliance (DC) Director.

These officials may not further redelegate this authority.

R. With respect to concluding international arrangements including international agreements, Memorandums of Understanding (MOUs), Confidentiality Commitments, and other related or similar documents, the Deputy Commissioner for Policy, Legislation, and International Affairs and the Associate Commissioner for Global Policy and Strategy are authorized to perform the functions of the Commissioner. These authorities may not be further redelegated.

S. The Deputy Commissioner for Human Foods is authorized to perform all of the functions of the Commissioner with respect to human foods, or that fall under the purview of the Human Foods Program. This authority includes the authority to issue responses to the following matters under 21 CFR part 10 as they pertain to human foods:

(1) Requests for waiver, suspension, or modification of procedural requirements under 21 CFR 10.19.

(2) Citizen petitions under 21 CFR 10.30.

(3) Petitions for reconsideration under 21 CFR 10.33.

(4) Petitions for stay under 21 CFR 10.35.

(5) Requests for advisory opinions under 21 CFR 10.85.

**2. Redelegation.**

These officials may not further redelegate these authorities except where specified.

**3. Effective Date.**

The Commissioner of Food and Drugs approved this delegation, via memorandum, on 17 February 2022 and changed the delegation to add Section 1.S. approved by the Commissioner on 26 January 2024.

| Status | Date Approved | Location of Change History | Contact | Approving Official |
|---|---|---|---|---|
| Initial | 06/15/2006 | N/A | OA/ OM/ OMP | Andrew C. von Eschenbach, M.D. Commissioner of Food and Drugs |

| Status | Date Approved | Location of Change History | Contact | Approving Official |
|---|---|---|---|---|
| Revision | 05/15/2007 | N/A | OA/ OM/ OMP | Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs |
| Revision | 12/07/2009 | N/A | OA/ OM/ OMP | Margaret A. Hamburg, M.D. Commissioner of Food and Drugs |
| Revision | 06/08/2010 | N/A | OA/ OM/ OMP | Margaret A. Hamburg, M.D. Commissioner of Food and Drugs |
| Revision | 10/11/2011 | N/A | OA/ OM/ OMP | Margaret A. Hamburg, M.D. Commissioner of Food and Drugs |
| Revision | 07/05/2012 | N/A | OO/ OBS/ MASS | Margaret A. Hamburg, M.D. Commissioner of Food and Drugs |
| Revision | 09/21/2016 | N/A | OO/ OHR/ MASS | Robert M. Califf, M.D., MACC Commissioner of Food and Drugs |
| Change | 10/29/2018 | 1.F. | OO/ OFBA/ OB | Scott Gottlieb, M.D. Commissioner of Food and Drugs |
| Revision | 12/31/2020 | N/A | OO/ OFBAP/ OPERM | Stephen M. Hahn, M.D. Commissioner of Food and Drugs |
| Revision | 02/17/2022 | NA | OO/ OFBAP/ OPERM | Robert M. Califf, M.D., MACC Commissioner of Food and Drugs |
| Change | 01/26/2024 | 1.S. and 1.F. | OO/ OFBAP/ OPERM | Robert M. Califf, M.D., MACC Commissioner of Food and Drugs |