SMG 1410.104

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Drugs

New Drug Applications, Abbreviated New Drug Applications, and their Supplements

Effective Date: 30 March 2026

1. Authority Delegated and To Whom Delegated.

All New Drug Applications, Abbreviated New Drug Applications, and Their Supplements:

A. The officials listed below are authorized, for drugs under their jurisdiction, to perform all functions of the Commissioner of Food and Drugs (Commissioner) with regard to approval of new drug applications, abbreviated new drug applications (ANDAs), and supplements for drugs for human use submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 355) and regulatory actions for drugs for human use for which approved applications, submitted under section 505 of the FDCA, are in effect:

(1) Center for Drug Evaluation and Research (CDER) Director, Deputy Directors, and Associate Directors.

(2) CDER/Office of Generic Drugs (OGD) Director and Deputy Directors.

(3) CDER/Office of New Drugs (OND) Director and Deputy Directors.

(4) CDER/OND/Office of Cardiology, Hematology, Endocrinology, and Nephrology (OCHEN) Director and Deputy Directors.

(5) CDER/OND/Office of Infectious Diseases (OID) Director and Deputy Directors.

(6) CDER/OND/Office of Immunology and Inflammation (OII) Director and Deputy Directors.

(7) CDER/OND/Office of Neuroscience (ON) Director and Deputy Directors.

(8) CDER/OND/Office of Nonprescription Drugs (ONPD) Director and Deputy Directors.

(9) CDER/OND/Office of Oncologic Diseases (OOD) Director and Deputy Directors.

(10) CDER/OND/Office of Rare Diseases, Pediatrics, Urology, and Reproductive Medicine (ORPURM) Director and Deputy Directors.

(11) CDER/OND/Office of Specialty Medicine (OSM) Director and Deputy Directors.

(12) CDER/Office of Pharmaceutical Quality (OPQ) Director and Deputy Directors.

(13) CDER/Office of Surveillance and Epidemiology (OSE) Director and Deputy Directors.

(14) CDER/OSE/Office of Medication Error Prevention and Risk Management (OMEPRM) Directors, Deputy Directors, and Associate Directors.

(15) CDER/OSE/Office of Pharmacovigilance and Epidemiology (OPE) Directors, Deputy Directors, and Associate Directors.

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

(17) CBER/Office of Blood Research and Review (OBRR) Director and Deputy Directors.

(18) CBER/Office of Therapeutic Products (OTP) Director and Deputy Directors.

(19) CBER/Office of Vaccines Research and Review (OVRR) Director and Deputy Directors.

Non-NME NDAs:

B. The officials listed below are authorized, for drugs under their jurisdiction, to perform all functions of the Commissioner with regard to:

- approval of new drug applications for drug products other than those that contain new molecular entities (NME) and;
- approval of supplements to approved new drug applications for drugs for human use submitted under 21 CFR 314.70 and;
- regulatory actions related to drugs for human use for which approved new drug applications are in effect.

The applications to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in this delegation's sections A and B and in the delegation of authority published in SMG 1410.10.

(1) CDER/OND/OCHEN Division Directors, Division Deputy Directors, and Division Associate Directors.

(2) CDER/OND/OID Division Directors, Division Deputy Directors, and Division Associate Directors.

(3) CDER/OND/OII Division Directors, Division Deputy Directors, and Division Associate Directors.

(4) CDER/OND/ON Division Directors, Division Deputy Directors, and Division Associate Directors.

(5) CDER/OND/ONPD Division Directors, Division Deputy Directors, and Division Associate Directors.

(6) CDER/OND/OOD Division Directors, Division Deputy Directors, and Division Associate Directors.

(7) CDER/OND/ORPURM Division Directors, Division Deputy Directors, and Division Associate Directors.

(8) CDER/OND/OSM Division Directors, Division Deputy Directors, and Division Associate Directors.

(9) CDER/OSE/OMEPRM Division Directors, Division Deputy Directors, and Division Associate Directors.

(10) CDER/OSE/OPE Division Directors, Division Deputy Directors, and Division Associate Directors.

All ANDAs and Certain Section 505(b)(2) NDAs:

C. The officials listed below are authorized, for drugs under their jurisdiction, to perform all functions of the Commissioner with regard to:

- approval of ANDAs submitted pursuant to 505(j) of the FDCA (21 U.S.C. 355(j)), and their supplements, for drugs for human use, and new drug applications submitted pursuant to section 505(b)(2) of the FDCA (21 U.S.C. 355(b)(2)) (section 505(b)(2) applications), and their supplements and;
- regulatory actions related to these drugs for human use for which approved applications are in effect.

The applications to which this authorization applies may continue to be acted upon by the officials so authorized in this delegation's sections A and B and in the delegation of authority published in SMG 1410.10.

(1) CDER/OGD/Office of Bioequivalence (OB) Director and Deputy Director.

(2) CDER/OGD/Office of Regulatory Operations (ORO) Director and Deputy Director.

(3) CDER/OGD/Office of Safety and Clinical Evaluation (OSCE) Director and Deputy Director.

(4) CDER/OND/OCHEN Division Directors, Division Deputy Directors, and Division Associate Directors

(5) CDER/OND/OID Division Directors, Division Deputy Directors, and Division Associate Directors.

(6) CDER/OND/OII Division Directors, Division Deputy Directors, and Division Associate Directors.

(7) CDER/OND/ON Division Directors, Division Deputy Directors, and Division Associate Directors.

(8) CDER/OND/ONPD Division Directors, Division Deputy Directors, and Division Associate Directors.

(9) CDER/OND/OOD Division Directors, Division Deputy Directors, and Division Associate Directors.

(10) CDER/OND/ORPURM Division Directors, Division Deputy Directors, and Division Associate Directors.

(11) CDER/OND/OSM Division Directors, Division Deputy Directors, and Division Associate Directors.

(12) CDER/OSE/OMEPRM Division Directors, Division Deputy Directors, and Division Associate Directors.

(13) CDER/OSE/OPE Division Directors, Division Deputy Directors, and Division Associate Directors.

NDA CMC Supplements without Clinicial Review:

D. The officials listed below are authorized, for drugs under their jurisdiction, to perform all functions of the Commissioner with respect to:

- approval of chemistry, manufacturing, and controls (CMC) supplements to new drug applications for drugs for human use that are described in 21 CFR sections 314.70, (b)(2)(i) through (b)(2)(iv), (b)(2)(vi) through (b)(2)(viii), (c)(1), (c)(2), and (c)(6)(i) through (c)(6)(ii), and
- regulatory actions related to these drugs for human use for which approved supplements to new drug applications are in effect.

The supplements to which this authorization applies may continue to be acted upon by the officials so authorized in this delegation's sections A, B, and C and in the delegation of authority published in SMG 1410.10.

(1) CDER/OPQ/Office of Pharmaceutical Manufacturing Assessment (OPMA) Director, Deputy Director, Division Directors, and Supervisors.

(2) CDER/OPQ/Office of Product Quality Assessment I (OPQA I) Director, Deputy Director, Division Directors, and Supervisors.

(3) CDER/OPQ/Office of Product Quality Assessment II (OPQA II) Director, Deputy Director, Division Directors, and Supervisors.

(4) CDER/OPQ/Office of Product Quality Assessment III (OPQA III) Director, Deputy Director, Division Directors, and Supervisors.

(5) CDER/OPQ/Office of Program and Regulatory Operations (OPRO) Director, Deputy Director, Division Directors, Supervisors, and Associate Director for Regulatory Affairs.

ANDA CMC Supplements:

E. The officials listed below, for drugs under their jurisdiction, are authorized to perform all functions of the Commissioner with respect to:

- approval of CMC supplements to ANDAs for drugs for human use that are described in 21 CFR 314.70(b)(2)(i) through (b)(2)(iv), (b)(2)(vi) through (b)(2)(viii) , (c)(1), (c)(2), and (c)(6)(i) through (c)(6)(ii), and 314.97, and
- regulatory actions related to these drugs for human use for which approved applications are in effect,

The supplements to which this authority applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in this delegation's sections A, B, and C and in the delegation of authority published in SMG 1410.10.

(1) CDER/OPQ/OPMA Director, Deputy Director, Division Directors, and Supervisors

(2) CDER/OPQ/OPQA I Director, Deputy Director, Division Directors, and Supervisors.

(3) CDER/OPQ/ OPQA II Director, Deputy Director, Division Directors, and Supervisors.

(4) CDER/OPQ/OPQA III Director, Deputy Director, Division Directors, and Supervisors.

(5) CDER/OPQ/OPRO Director, Deputy Director, Division Directors, Supervisors, and Associate Director for Regulatory Affairs.

ANDA and NDA Labeling Supplements:

F. The officials listed below are authorized, for drugs under their jurisdiction, to perform all functions of the Commissioner with respect to approval of labeling supplements to new drug applications and ANDAs for drugs for human use under their jurisdiction, and assigned to their respective organizations, that are described in 21 CFR 314.70(b)(2)(v) and (c)(6)(iii) and 314.97.

The supplements to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in this delegation's sections A, B, and C, and in the delegation of authority published in SMG 1410.10.

(1) CDER/OGD/ORO/Division of Labeling Review (DLR) Director and Deputy Director.

(2) CDER/OPQ/OPMA Director, Deputy Director, Division Directors, and Supervisors

(3) CDER/OPQ/OPQA I Director, Deputy Director, Division Directors, and Supervisors.

(4) CDER/OPQ/ OPQA II Director, Deputy Director, Division Directors, and Supervisors.

(5) CDER/OPQ/OPQA III Director, Deputy Director, Division Directors, and Supervisors.

(6) CDER/OPQ/OPRO Director, Deputy Director, Division Directors, Supervisors, and Associate Director for Regulatory Affairs.

All NDAs, ANDAs, and Supplements:

G. The officials listed below are authorized, for drugs under their jurisdiction, to perform all functions of the Commissioner with respect to regulatory actions related to the review of proprietary names requests and for waivers of postmarket safety reporting requirements under 21 CFR 314.80 or 21 CFR 314.98, that are the subject of a new drug application, ANDA, or supplement submitted or approved under section 505 of the FDCA:

(1) CDER/OND Directors and Deputy Directors

(2) CDER/OND/OCHEN Director, Deputy Directors, Division Directors, Division Deputy Directors, and Division Associate Directors.

(3) CDER/OND/OID Director, Deputy Directors, Division Directors, Division Deputy Directors, and Division Associate Directors.

(4) CDER/OND/OII Director, Deputy Directors, Division Directors, Division Deputy Directors, and Division Associate Directors.

(5) CDER/OND/ON Director, Deputy Directors, Division Directors, Division Deputy Directors, and Division Associate Directors.

(6) CDER/OND/ONPD Director, Deputy Directors, Division Directors, Division Deputy Directors, and Division Associate Directors.

(7) CDER/OND/OOD Director, Deputy Directors, Division Directors, Division Deputy Directors, and Division Associate Directors.

(8) CDER/OND/ORPURM Director, Deputy Directors, Division Directors, Division Deputy Directors, and Division Associate Directors.

(9) CDER/OND/OSM Director, Deputy Directors, Division Directors, Division Deputy Directors, and Division Associate Directors.

(10) CDER/OSE Directors and Deputy Directors

(11) CDER/OSE/OMEPRM Directors, Deputy Directors, Office Associate Directors, Division Directors, Deputy Division Directors, and Division Associate Director.

The actions to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in this delegation's sections A, B, and C, and in the delegation of authority published in SMG 1410.10.

2. Redelegation.

These officials may not further redelegate these authorities.

3. Effective Date.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on 30 March 2026.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	04/29/2009	N/A	CDER/ OM/ DMB	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	06/12/2012	N/A	OMPT/ CDER/ OM/ DMB	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	03/30/2026	N/A	CDER/ ORP	Martin A. Makary, M.D., M.P.H. Commissioner of Food and Drugs