

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - HUMAN DRUGS

APPROVAL OF NEW DRUG APPLICATIONS AND THEIR SUPPLEMENTS

Effective Date: 06/12/2012

1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED

A. Except for drugs listed in 21 CFR Part 314, Section 314.440(b), the following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) with regard to approval of new drug applications and supplements for drugs for human use that have been submitted under Section 505 of the Federal Food, Drug and Cosmetic Act (the Act) (21 U.S.C. 355), and regulatory actions for drugs for human use for which approved applications, submitted under Section 505 of the Act, are in effect.

1. Director and Deputy Directors, Center for Drug Evaluation and Research (CDER), Office of Medical Products and Tobacco (OMPT)
2. Directors and Deputy Directors, Office of New Drugs (OND), Office of Pharmaceutical Science (OPS), and Office of Surveillance and Epidemiology (OSE), CDER, OMPT
3. For drugs under their jurisdiction, Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, and IV, Office of Antimicrobial Products and Office of Hematology and Oncology Products, OND, CDER, OMPT

B. For drugs listed in 21 CFR Part 314, Section 314.440(b), the following officials are authorized to perform all the functions of the Commissioner with regard to approval of new drug applications and supplements for drugs for human use that have been submitted under Section 505 of the Act, and regulatory actions for drugs for human use for which approved applications, submitted under Section 505 of the Act, are in effect:

1. Director, Deputy Director, and Associate Director for Review Management, Center for Biologics Evaluation and Research (CBER), OMPT

2. Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, and Office of Cellular, Tissue and Gene Therapies, CBER, OMPT
- C. The following officials are authorized, for drugs under their jurisdiction, to perform all functions of the Commissioner with regard to (1) approval of supplemental applications to approved new drug applications for drugs for human use that have been submitted under 21 CFR Part 314, Section 314.70 and of new drug applications for drug products other than those that contain new molecular entities (new chemical entities), and (2) regulatory actions related to drugs for human use for which approved applications, submitted under 21 CFR Part 314, Section 314.70, other than those that contain new molecular entities (new chemical entities), 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 delegations of authority published in SMG 1410.10 and paragraphs A and B of SMG 1410.104.

1. Directors and Deputy Directors of the Divisions in the Offices of Drug Evaluation I, II, III, and IV, Office of Antimicrobial Products and Office of Hematology and Oncology Products, OND, CDER, OMPT
- D. The following officials are authorized to perform all the functions of the Commissioner with regard to: (1) approval of abbreviated new drug applications and supplements for drugs for human use and new drug applications for drugs with a 5S classification whose clinical safety and efficacy may be supported by appropriate literature citations in lieu of submission of data from original proprietary studies, or Section 505(b)(2) of the Act (21 U.S.C. 355 (b)(2)) applications under their jurisdiction, and (2) regulatory actions related to these drugs for human use for which approved 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 delegations of authority published in SMG 1410.10 and paragraphs A. and B. of SMG 1410.104.

1. For drugs submitted under Sections 314.50, 314.70, and 314.94 of 21 CFR, Part 314, except for those drug products listed in 21 CFR, Part 314, Section 314.440(b):
 - a. Director and Deputy Director, Office of Generic Drugs (OGD), Office of Pharmaceutical Science, CDER, OMPT, except that the Director and Deputy Director, OGD are not authorized to approve

new drug applications with a 5S classification if clinical studies are needed.

- b. Directors and Deputy Directors of the divisions in Offices of Drug Evaluation I, II, III, and IV, Office of Antimicrobial Products (OAP) and Office of Hematology and Oncology Products (OHOP), Office of New Drugs, CDER, OMPT.
 2. For drug products listed in 21 CFR, Part 314, Section 314.440(b) and submitted under 21 CFR, Part 314, Sections 314.50, 314.70, and 314.94:
 - a. Directors and Deputy Directors, Office of Blood Research and Review; Office of Vaccines Research and Review; Office of Cellular, Tissue and Gene Therapies; Office of Compliance and Biologics Quality, CBER, OMPT
 - b. Director and Deputy Director, Office of New Drugs, CDER, OMPT
- E. The following officials are authorized to perform all functions of the Commissioner with respect to: (1) approval of supplemental applications to abbreviated new drug applications, 5S applications, or section 505(b)(2) applications for drugs for human use that are described in 21 CFR, Part 314, Sections 314.70(b)(1), (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) (authority to approve supplements that require in vivo bioavailability studies or that include in vivo bioavailability study waiver requests is not included in this paragraph), and (2) regulatory actions related to these drugs for human use for which approved applications are in effect:
 1. Director and Deputy Director, Division of Chemistry I, Office of Generic Drugs, OPS, CDER, OMPT
 2. Director and Deputy Director, Division of Chemistry II, Office of Generic Drugs, OPS, CDER, OMPT
 3. Director and Deputy Director, Division of Chemistry III, Office of Generic Drugs, OPS, CDER, OMPT
 4. Director and Deputy Director, Division of Chemistry IV, Office of Generic Drugs, OPS, CDER, OMPT
- F. The following officials are authorized to perform all the functions of the Commissioner with respect to: (1) approval of supplemental applications to abbreviated new drug applications, 5S applications, or section 505(b)(2) applications for drugs for human use that are described in 21 CFR, Part

314, Sections 314.70(b)(2)(v) and (c)(6)(iii), and (2) regulatory actions related to these drugs for human use for which approved applications are in effect.

Authority to approve supplements that require in vivo bioavailability studies or in vivo study waiver requests is not included in this delegation.

1. Director, Division of Labeling and Program Support, Office of Generic Drugs, OPS, CDER, OMPT

G. The following officials are authorized to perform all functions of the Commissioner with respect to: (1) approval of supplemental applications to new drug applications for drugs for human use that are described in 21 CFR, Part 314, Sections 314.70(b)(1), (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 (2) regulatory actions related to these drugs for human use for which approved supplemental applications to new drug applications are in effect.

Authority to approve supplements that require in vivo bioavailability information or that require a change in the labeling of the drug, except changes that reflect only the use of a different facility or establishment, is not included in this delegation.

The supplemental applications to which this authorization applies may continue to be acted upon by the officials so authorized in delegations of authority published in SMG 1410.10 and paragraphs A, B and C of SMG 1410.104.

1. Director and Deputy Director, Office of New Drug Quality Assessment (ONDQA), OPS, CDER, OMPT
2. Directors and Deputy Directors, Division of New Drug Quality Assessment I, II, and III, ONDQA, OPS, CDER, OMPT
3. Branch Chiefs, Branch I, II, and III, Division of New Drug Quality Assessment I, ONDQA, OPS, CDER, OMPT
4. Branch Chiefs, Branch IV, V, and VI, Division of New Drug Quality Assessment II, ONDQA, OPS, CDER, OMPT
5. Branch Chiefs, Branch VII, VIII, and IX, Division of New Drug Quality Assessment III, ONDQA, OPS, CDER, OMPT

H. The following officials are authorized to take regulatory actions related to the approval of drugs for human use that are the subject of an investigational new drug application (IND), new drug application (NDA),

abbreviated new drug application (ANDA), or biologics license application (BLA) for biologics under their jurisdiction, and supplements submitted or approved under the Act:

1. Director and Deputy Director, Office of Surveillance and Epidemiology (OSE), CDER, OMPT
 2. Directors and Deputy Directors, Office of Medication Error Prevention and Risk Management (OMEPRM), and Office of Pharmacovigilance and Epidemiology (OPE), OSE, CDER, OMPT.
 3. Directors and Deputy Directors, Division of Risk Management and Division of Medication Error Prevention and Analysis, OMEPRM, and the Directors and Deputy Directors, Divisions of Epidemiology I and II, and Divisions of Pharmacovigilance I and II, OPE, OSE, CDER, OMPT
- I. The following officials are authorized to take regulatory actions related to the review of proprietary names for drugs for human use that are the subject of an investigational new drug application (IND), new drug application (NDA), abbreviated new drug application (ANDA), or biologics license application (BLA) for biologics under their jurisdiction, and supplements submitted or approved under the Act:
1. Director and Deputy Director, OSE, CDER, OMPT
 2. Director and Deputy Director, OMEPRM, OSE, CDER, OMPT
 3. Director and Deputy Director, Division of Medication Error Prevention and Analysis, OMEPRM, OSE, OMPT

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 June 12, 2012.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	04/29/2009	N/a	CDER/OM	Commissioner of Food and Drugs
Revision	06/12/2012	N/a	OO/OBS	Commissioner of Food and Drugs