SMG 1410.702

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY – PRODUCT DESIGNATION

PREMARKET APPROVAL OF A PRODUCT THAT IS OR CONTAINS A BIOLOGIC, A DEVICE, OR A DRUG

Effective Date: June 23, 2015

1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED.

A. The following Officials who currently hold delegated premarket approval authority for biologics, devices, or drugs, respectively, are hereby delegated all authorities necessary for premarket approval of any product that is a biologic, a device, or a drug, or any combinations of two or more of these products:

1. Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), Office of Medical Products and Tobacco, (OMPT).

2. Directors, Office of Blood Research and Review, CBER, OMPT.

3. Directors, Office of Vaccines Research and Review, CBER, OMPT.

4. Directors, Office of Cellular, Tissue and Gene Therapies, CBER, OMPT.

5. Directors, Office of Compliance and Biologics Quality, CBER, OMPT.

6. Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), OMPT.

7. Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH, OMPT.

8. Director, Program Operations Staff (POS), ODE, CDRH, OMPT.

9. Division Directors, ODE, CDRH, OMPT.

10. Director and Deputy Directors, Office of Compliance (OC), CDRH, OMPT.

11. Division Directors, OC, CDRH, OMPT.

12. Director and Deputy Directors, Office of In Vitro Diagnostics and Radiological Health (OIR), CDRH, OMPT.

13. Division Directors, OIR, CDRH, OMPT.

B. The following Officials are authorized to approve, disapprove, or withdraw approval of supplemental premarket applications:

1. Director, POS, ODE, CDRH, OMPT.

2. Chief, Premarket Approval Section, POS, ODE, CDRH, OMPT.

3. Division Directors, ODE, CDRH, OMPT.

4. Director and Deputy Directors, OIR, CDRH, OMPT.

5. Division Directors, OIR, CDRH, OMPT.

6. Director and Deputy Directors, Office of Surveillance and Biometrics (OSB), CDRH, OMPT.

7. Division Directors, OSB, CDRH, OMPT.

8. Director and Deputy Directors, Center for Drug Evaluation and Research (CDER), OMPT.

9. Director and Deputy Director, Office of New Drugs (OND), CDER, OMPT.

10. Director, Office of Generic Drugs, CDER, OMPT.

11. Director, Office of Pharmaceutical Quality, CDER, OMPT.

12. Director, Offices of Drug Evaluation I, II, III, CDER, OMPT.

13. Director, Office of Antimicrobial Products, CDER, OMPT.

14. Director, Office of Nonprescription Products, CDER, OMPT.

15. Director, Office of Oncology Drug Products, OND, CDER, OMPT.

2. RE-DELEGATION.

These Officials may not further re-delegate these authorities.

3. EFFECTIVE DATE.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on June 23, 2015.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	01/05/2010	N/a	CDRH/OMO/ DEMO/AMB	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	06/23/2015	N/a	CDRH/OMO/ DEMO/AMB	Stephen Ostroff, M.D. Acting Commissioner of Food and Drugs