SMG 1410.701

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - PRODUCT DESIGNATION

AUTHORITY RELATING TO DETERMINATION OF PRODUCT PRIMARY JURISDICTION

Effective Date: 06/04/2010

1. AUTHORITY DELEGATED

A. To make a determination, including under section 563 of the Federal Food, Drug, and Cosmetic Act (the act) (21 USC 360bbb-2) respecting the classification of a product as a drug, biological product, device, or combination product subject to section 503(g) of the act (21 U.S.C. 353(g)), or respecting the assignment for a component of the Food and Drug Administration that will regulate a drug, biological product, device or combination product

B. To make determinations under section 503(g) of the act (21 U.S.C. 353(g)) of the primary mode of action of a combination product and to assign an agency component for premarket review and regulation of each such product

2. TO WHOM DELEGATED.

A. Director, Office of Combination Products (OCP), Office of Special Medical Programs (OSMP), Office of the Commissioner (OC)

B. Product Assignment Officer, OCP,OSMP, OC

C. Product Classification Officer, OCP, OSMP, OC

3. REDELEGATION.

These officials may not further redelegate this authority.

4. EFFECTIVE DATE.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on June 4, 2010.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	06/04/2010	N/a	OC/OSMP/OCP	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs