SMG 1410.113

FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF AUTHORITY

REGULATORY - HUMAN DRUGS

DRUG AND BIOLOGICAL PRODUCT SHORTAGES

Effective Date: May 5, 2014

1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED.

A. The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs (Commissioner) under section 506C (except section 506C(e)) of the Federal, Food, Drug & Cosmetic Act (FD&C Act) (21 U.S.C. 356c) including receiving and responding to notifications of a discontinuance or interruption in manufacturing of certain products (expediting inspections or review of applications), distributing information on such discontinuances or interruptions in manufacturing, and issuing notices of noncompliance with section 506C:

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

2. Associate Director for Drug Shortages, CDER, OMPT.

3. Program Coordinator for Drug Shortages, CDER, OMPT.

4. Directors and Deputy Directors, Office of New Drugs (OND) and Office of Generic Drugs (OGD), CDER, OMPT.

5. Director and Deputy Directors, Office of Compliance, CDER, OMPT.

6. Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), OMPT.

7. Director and Deputy Director, Office of Compliance and Biologics Quality, CBER, OMPT.

B. The following officials are authorized to perform all the functions of the Commissioner under section 506C(e) of the FD&C Act (21 U.S.C. 356c(e)) and section 306(h) of the Controlled Substances Act (21 U.S.C. 826), including coordinating with the Attorney General on shortages of controlled substances and publishing certain quota denial letters from the Attorney General:

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

2. Associate Director for Drug Shortages, CDER, OMPT.

3. Director, Controlled Substances Staff, CDER, OMPT.

4. Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), OMPT.

5. Director and Deputy Director, Office of Compliance and Biologics Quality, CBER, OMPT.

C. The following officials are authorized to perform all the functions of the Commissioner under section 506D(b), 506D(c), and 506D(d) of the FD&C Act (21 U.S.C. 356D(b), (c), (d)) including communication and consultation prior to an enforcement action or warning letter and establishing a mechanism for third parties to report evidence of a drug shortage:

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

2. Associate Director for Drug Shortages, CDER, OMPT.

3. Directors and Deputy Directors, Office of New Drugs (OND) and Office of Generic Drugs (OGD), CDER, OMPT.

4. Director and Deputy Directors, Office of Compliance, CDER, OMPT.

5. Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), OMPT.

6. Director and Deputy Director, Office of Compliance and Biologics Quality, CBER, OMPT.

D. The following officials are authorized to perform all the functions of the Commissioner under section 506E of the FD&C Act (21 U.S.C. 356E) including maintaining a drug shortages list:

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

2. Associate Director for Drug Shortages, CDER, OMPT.

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

4. Director and Deputy Director, Office of Compliance and Biologics Quality, CBER, OMPT.

2. REDELEGATION.

These officials may not further redelegate this authority.

3. EFFECTIVE DATE.

These delegations become effective upon date of signature. In addition, I hereby ratify and affirm any actions taken by you or your subordinate(s), which in effect involved the exercise of the authorities delegated herein prior to the effective date of this delegation.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on May 5, 2014.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	05/05/2014	N/a	CDER/OM	Commissioner of Food and Drugs
Change	06/25/2014	SMG number	OHR/MASS	Commissioner of Food and Drugs