SMG 1410.116

FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF AUTHORITY

REGULATORY – HUMAN DRUGS

WAIVERS, EXCEPTIONS, AND EXEMPTIONS PERTAINING TO THE DRUG SUPPLY CHAIN SECURITY ACT

Effective Date: February 18, 2016

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The following officials are authorized to perform all waiver, exception, and exemption functions of the Commissioner of Food and Drugs (Commissioner) under Section 582(a)(3)(A) of the Federal, Food, Drug & Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1(a)(3)(A)):

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

2. Director and Deputy Directors, Office of Compliance (OC), CDER, OMPT.

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

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

These authorities include:

- Granting, under Section 582(a)(3)(A)(i) of the FD&C Act, a waiver for authorized manufacturers, re-packagers, wholesale distributors, or dispensers from any of the requirements set forth in Section 582 of the FD&C Act, if such requirements would result in an undue economic hardship or for emergency medical reasons, including a public health emergency declaration pursuant to Section 319 of the Public Health Service Act;

- Making determinations, under Section 582(a)(3)(A)(ii) of the FD&C Act, regarding an exception for a manufacturer or re-packager to the requirements relating to product identifiers if a product is packaged in a container too small or otherwise unable to

accommodate a label with sufficient space to bear the information required for compliance with Section 582 of the FD&C Act; or

- Making determinations, under Section 582(a)(3)(A)(iii) of the FD&C Act, regarding the exemption of other products or transactions from the requirements of Section 582 of the FD&C Act.

B. The following officials are authorized to perform all functions of the Commissioner of Food and Drugs (Commissioner) under Section 582(a)(3)(B) of the FD&C Act (21 U.S.C. 360eee-1(a)(3)(B)):

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

2. Director and Deputy Directors, Office of Compliance (OC), CDER, OMPT.

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

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

These authorities include biennially reviewing and renewing, as applicable:

- Waivers granted under Section 582(a)(3)(A)(i) of the FD&C Act;

- Exemptions determined under Section 582(a)(3)(A)(ii) of the FD&C Act; and

- Exemptions determined under Section 582(a)(3)(A)(iii) of the FD&C Act.

C. The following officials are authorized to perform the waiver functions of the Commissioner of Food and Drugs (Commissioner) under Section 582(g)(2)(B)(ii) of the FD&C Act (21 U.S.C. 360eee-1(g)(2)(B)(ii)):

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

2. Director and Deputy Directors, Office of Compliance (OC), CDER, OMPT.

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

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

These authorities include:

- Making determinations regarding waivers to dispensers from any of the requirements set forth in Section 582(g)(1) if such requirements would result in an undue economic hardship, and

- Reviewing such determinations biennially and renewing waivers as appropriate.

2. REDELEGATION.

These officials may not further redelegate this authority.

3. EFFECTIVE DATE.

The Acting Commissioner of Food and Drugs approved this delegation on February 18, 2016.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	02/18/2016	N/a	CBER/OCBQ and CDER/OC/ODSIR/ DSCI/SCSPB	Stephen M. Ostroff, M.D., Acting Commissioner of Food and Drugs