SMG 1410.802

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - IMPORTS AND EXPORTS

EXPORT OF UNAPPROVED DRUGS

Effective Date: 06/10/2011

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The following officials are authorized, under Section 802(b)(2) and (b)(3) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 382(b)(2) and (b)(3), to grant or deny petitions to export unapproved new drugs and biological products and to issue notices of receipt of such petitions for human drugs assigned to their respective organizations:

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

2. Director and Deputy Director, Office of Compliance and Biologics Quality, CBER

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

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

B. The following officials are authorized, under Section 802(e) of the Act (21 U.S.C. 382(e)), to approve or disapprove an application to export a drug (including a biological product) to be used in the prevention or treatment of a tropical disease or another disease as described in Section 802(e) for human drugs assigned to their respective organizations:

1. Director and Deputy Director, CBER

2. Director and Deputy Director, Office of Compliance and Biologics Quality, CBER

3. Director and Deputy Directors, CDER

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

C. The following officials are authorized, under Section 351(h) of the Public Health Service Act (42 U.S.C. 262(h)), to approve or disapprove an application to export a partially processed biological product:

1. Director and Deputy Director, CBER

2. Director and Deputy Director, Office of Compliance and Biologics Quality, CBER

3. Director and Deputy Directors, CDER

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

2. REDELEGATION.

These officials may not further redelegate this authority.

3. EFFECTIVE DATE.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on June 10, 2011.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	06/10/2011	N/a	CBER/OM	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs