

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – General Redelegations

Disclosure of Trade Secret Information to Foreign Governments

Effective Date: 05/30/2019

1. Authority Delegated and To Whom Delegated.

- A. The officials listed below are authorized to perform all the functions of the Commissioner of Food and Drugs pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379(c)(3)) Section 708(c)(3). Such officials may disclose such information directly or may authorize such disclosure and designate agency members to transmit such information to the foreign government on the official's behalf whether for an individual disclosure or a series of disclosures at the discretion of the official.
- (1) Center for Biologics Evaluation and Research (CBER) Director and Deputy Directors.
 - (2) CBER/Office of Compliance and Biologics Quality (OCBQ) Director and Deputy Directors.
 - (3) CBER/Office of Communications, Outreach, and Development (OCOD) Director and Deputy Director.
 - (4) Center for Drug Evaluation and Research (CDER) Director and Deputy Directors.
 - (5) CDER/Office of Compliance (OC) Director and Deputy Directors.
 - (6) CDER/OC/Office of Manufacturing Quality (OMQ) Director and Deputy Directors.
 - (7) CDER/OC/Office of Drug Security, Integrity, and Response (ODSIR) Director and Deputy Directors.
 - (8) CDER/OC/Office of Scientific Investigations (OSI) Director and Deputy Director.
 - (9) CDER/Office of Pharmaceutical Quality (OPQ) Director and Deputy Director.
 - (10) CDER/OPQ/Office of Process and Facilities (OPF) Director and Deputy Director.
 - (11) CDER/OPQ/Office of Policy for Pharmaceutical Quality (OPPQ) Director and Deputy Director.
 - (12) CDER/OPQ/Office of Surveillance (OS) Director and Deputy Director.
 - (13) Center for Veterinary Medicine (CVM) Director and Deputy Directors.

- (14) CVM/Office of Surveillance and Compliance (OSC) Director and Deputy Director.
- (15) Office of Regulatory Affairs (ORA) Associate Commissioner for Regulatory Affairs and Deputy Associate Commissioner for Regulatory Affairs.
- (16) ORA/Office of Medical Products and Tobacco Operations (OMPTO) Assistant Commissioner for Medical Products and Tobacco Operations.
- (17) ORA/OMPTO/Office of Pharmaceutical Quality Operations (OPQO) Director and Deputy Director.
- (18) ORA/Office of Partnerships and Operational Policy (OPOP) Assistant Commissioner for Partnership and Policy.
- (19) ORA/OPOP/Office of Partnerships (OP) Director and Deputy Director.
- (20) ORA/OPOP/Office of Strategic Planning and Operational Policy (OSPOP) Director and Deputy Director.

2. Redelelegation.

These officials may not further redelegate this authority.

3. Effective Date.

The Acting Commissioner of Food and Drugs approved the delegations, via memorandum, on May 30, 2019.

STATUS	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	05/30/2019	N/a	OPLIA/ OGPS	Norman E. Sharpless, M.D. Acting Commissioner of Food and Drugs

[Back to Delegations of Authority, Volume II \(1400\)](#)