

SMG 1118A.43

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of the Commissioner

Office of Policy, Legislation and International Affairs

Office of Global Policy and Strategy

Office of Trade, Mutual Recognition, and International Agreements

Effective Date: December 14, 2018

1. Office of Trade, Mutual Recognition, and International Agreements (DCOCC).

- A. Advises and assists the Deputy Commissioner, the Associate Commissioner, and other key Food and Drug Administration (FDA) officials in addressing issues related to international trade of FDA regulated products.
- B. Serves as the FDA lead and final clearing for negotiations and policy development related to Free Trade Agreements (FTAs) and Trade and Investment Frameworks (TIFAs), policy development for the World Trade Organization (WTO) and its Committees, and interactions with the United States Trade Representative (USTR) on matters affecting FDA regulated products.
- C. Negotiates Mutual Recognition Agreements with foreign counterparts.
- D. Serves as the FDA focal point and final clearing for formal arrangements with foreign counterparts, e.g., memoranda of understanding, mutual recognition agreements, exchange of letters, partnerships, and confidentiality commitments.
- E. Serves as the FDA focal point and final clearing for policies and procedures pertaining to sharing public and non-public information with international counterpart agencies, and, in conjunction with the Regulatory Affairs program, for import/export policy issues.

2. Authority and Effective Date.

The functional statements for the Office of Trade, Mutual Recognition, and International Agreements were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Policy, Legislation and International Affairs, Office of Global Policy and Strategy, Office of Trade, Mutual Recognition, and International Agreements organization structure depicting all the organizational structures reporting to the Director.

Office of Trade, Mutual Recognition, and International Agreements (DCOCC)