

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 and Global Partnerships

Effective Date: 09/30/2022

1. Office of Trade and Global Partnerships (DCOCC).

- A. Advises and assists the Deputy Commissioners, the Associate Commissioners, 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 authority for negotiations and policy development related to Free Trade Agreements (FTAs) and Trade and Investment Frameworks (TIFAs), and interactions with the United States Trade Representative (USTR) on matters affecting FDA regulated products.
- C. Leads the formation of global partnerships and engagement in international regulatory efforts to help ensure the quality and safety of FDA regulated products.
- D. Negotiates Mutual Recognition Agreements with foreign counterparts.
- E. Serves as FDA's lead for policy development and coordination for multi- and plurilateral organizations e.g. the World Health Organization its regional offices and other United Nations organizations, the World Bank, the World Trade Organization and its Committees, the Asia Pacific Economic Cooperation, and relevant global coalitions.
- F. 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.

G. 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 and Global Partnerships were approved by the Commissioner of Food and Drugs and effective on September 30, 2022.

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(DCOCC)

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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 and Global Partnerships organization structure depicting all the organizational structures reporting to the Director.

Office of Trade and Global Partnerships (DCOCC)