

SMG 1130A.1

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 Women’s Health

Effective Date: December 14, 2018

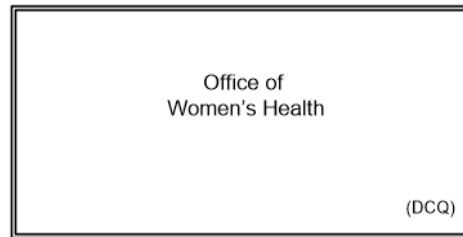
1. Office of Women’s Health (DCQ).

- A. Serves as the principal advisor to the Commissioner, the Chief Scientist, and other key Food and Drug Administration (FDA) officials on scientific, ethical, and policy issues relating to women's health.
- B. Provides leadership and policy direction for the FDA regarding issues of women's health and coordinates efforts to establish and advance a women's health agenda for the FDA.
- C. Monitors the inclusion of women in clinical trials and the implementation of guidelines concerning the representation of women in clinical trials and the completion of sex/gender analysis.
- D. Identifies and monitors the progress of crosscutting and multidisciplinary women's health initiatives including changing needs, areas that require study, and new challenges to the health of women as they relate to FDA's mission.
- E. Serves as the FDA's liaison with other agencies, industry, professional associations and advocacy groups with regard to the health of women.

2. Authority and Effective Date.

The functional statements for the Office of Women’s Health were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Women's Health organization structure depicting all the organizational structures reporting to the Assistant Commissioner for Women's Health.

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