

[Federal Register: July 28, 1994]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
[GN # 2260]

Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the **Statement of Organization, Functions, and Delegations of Authority** for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 56 FR 29484, June 27, 1991, as amended most recently in pertinent part at 58 FR 45111, August 26, 1993) is amended to reflect the establishment of the Office of Women's Health in the Office of External Affairs, Food and Drug Administration (FDA). The **organization** is being established to facilitate the Agency coordination and communication of women's health issues and initiatives.

Under Section HF-B, **Organization:**

1. Insert a new subparagraph under Office of External Affairs (HFAQ) reading as follows:

Office of Women's Health. Serves as the principal advisor to the Commissioner and other key officials on scientific, ethical, and policy issues relating to women's health.

Provides leadership and policy direction for the Agency regarding issues of women's health and coordinates efforts to establish and advance a women's health agenda for the Agency.

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 gender analysis.

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.

Serves as the Agency's liaison with other agencies, industry, and professional associations with regard to the health of women.

Dated: July 11, 1994.
David A. Kessler,
Commissioner of Food and Drugs.
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