

**SMG 1112A.1**

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administration**

**Office of the Commissioner**

**Oncology Center of Excellence**

Effective Date: December 14, 2018

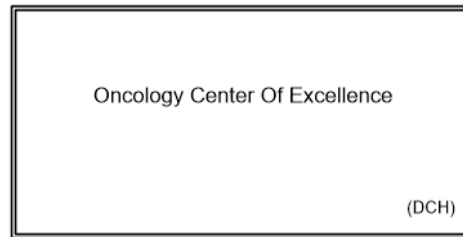
**1. Oncology Center of Excellence (DCH).**

- A. Directs the development of integrated strategies, plans, policies, and budgets to build a Center of Excellence that focuses on the strategic area of Oncology.
- B. Directs the Food and Drug Administration (FDA) efforts to build consistency and uniformity across the FDA in the evaluation and implementation of Oncology review by identifying and implementing specific strategies and objectives.
- C. Develops strategies and objectives to expedite the development of novel therapies by streamlining the FDA's regulatory capacity.
- D. Improves coordination between medical product Centers to enhance data sharing.
- E. Supports, develops and consolidates core competencies to focus on the scientific advancement for innovative cancer therapies and in-vitro diagnostics for all medical product Centers.
- F. Advances the FDA's oncology mission by combining skills of regulatory scientists and reviewers.
- G. Ensures regulation of products is more reflective of how they are used in medical practice.

**2. AUTHORITY AND EFFECTIVE DATE.**

The functional statements for the Oncology Center of Excellence 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, Oncology Center of Excellence organization structure depicting all the organizational structures reporting to the Director.

Oncology Center of Excellence (DCH)