

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Food Safety and Applied Nutrition

Office of Applied Research and Safety Assessment

Division of Toxicology

Effective Date: December 14, 2018

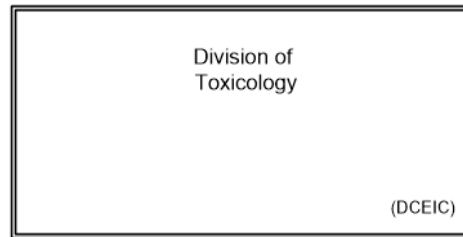
1. Division of Toxicology (DCEIC).

- A. Provides the Center and Food and Drug Administration (FDA) leadership in the areas of developmental/reproductive toxicology, hepatotoxicity and neuro-and immunotoxicology.
- B. Recommends, develops, coordinates and conducts research to assess the toxic effects of substances for which the Center has regulatory responsibilities and investigates mechanisms of the underlying toxicological reactions independently and in collaboration with other Centers, Agencies and entities in support of the Center's goals.
- C. Interacts, collaborates with and provides support to external programs in designing appropriate experiments which assess the toxic effects of substances for which the Center has regulatory responsibilities.
- D. Develops and/or validates systems that may serve to refine, reduce or replace animal models.
- E. Conducts toxicological studies which support the Center's regulatory responsibilities including: assessing and collecting data applicable to guideline development, the evaluation of petitions and proposals, the review of current tolerances, providing recommendations on toxicological product evaluation criteria, the review of protocols relating to the review and approval process of new substances and for the reaffirmation of marketed substances.

2. Authority and Effective Date.

The functional statements for the Division of Toxicology were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Applied Research and Safety Assessment, Division of Toxicology organization structure depicting all the organizational structures in the immediate office reporting to the Director.

Division of Toxicology (DCEIC)