

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 Compliance

Division of Enforcement

Effective Date: December 14, 2018

1. Division of Enforcement (DCEHA).

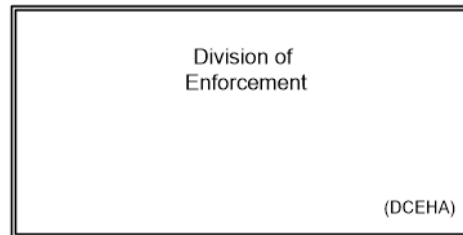
- A. Serves as the Center's point of contact for enforcement policy and priority inquiries, including recalls, from other Food and Drug Administration (FDA) units, industry, and other parties.
- B. Manages reviews of regulatory actions recommended by FDA field offices and other FDA components. Guides field offices activities, when necessary, in developing scientifically and legally supportable actions. Participates in case development strategy calls with the field and other FDA components.
- C. Works with other Center and FDA units to develop compliance and enforcement strategies to address cross-cutting regulatory issues or emerging compliance challenges. Develops innovative enforcement solutions to novel, complex, and precedent-setting regulatory problems.
- D. Evaluates import and domestic inspectional, investigational, and analytical evidence and determines whether to pursue a regulatory action or alternative remedy.
- E. Evaluates recall recommendations, obtains scientific and technical support to document health risks associated with recalled products, and ensures that recall actions are consistent with FDA and Center policies.
- F. Assists FDA legal offices and field units and the Department of Justice in developing legal documents including declarations, obtaining experts, responding to interrogatories, and providing trial or other requested assistance. Represents the Center at enforcement negotiations.

- G. Serves as an expert resource on foreign product compliance and participates in FDA discussions, decisions, and fact finding for import and international issues for foreign country, product, and industry assessments.
- H. Serves as the Center focal point for consumer complaints and daily Reportable Food Registry (RFR) / Risk Control Review activities. Maintains the Center RFR database and guides field follow-up to RFR reports.

2. Authority and Effective Date.

The functional statements for the Division of Enforcement 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, Center for Food Safety and Applied Nutrition, Office of Compliance, Division of Enforcement organization structure depicting all the organizational structures in the immediate office reporting to the Director.

Division of Enforcement (DCEHA)