

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Food and Cosmetics

**To Issue an Order Under Section 423(b) In The Context of a
Mandatory Food Recall**

Effective Date: 10 February 2020

1. Authority Delegated and To Whom Delegated.

A. The officials listed below are authorized to issue an order under Section 423(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. Section 350l(b)] where FDA determines that there is a reasonable probability that an article of food (other than infant formula) is adulterated under Section 402 of the FD&C Act [21 U.S.C. Section 342] or misbranded under Section 403(w) of the FD&C Act [21 U.S.C. Section 343(w)] and that the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals:

- (1) Center for Food Safety and Applied Nutrition (CFSAN) Director and Deputy Directors.
- (2) CFSAN/Office of Compliance (OC) Director and Deputy Director.
- (3) Office of Food Policy and Response (OFPR) Deputy Commissioner for Food Policy and Response and Associate Commissioners for Food Policy and Response.
- (4) Office of Regulatory Affairs (ORA) Associate Commissioner for Regulatory Affairs.
- (5) ORA/Office of Human and Animal Food Operations (OHAFO) Assistant Commissioner.
- (6) ORA/OHAFO/Office of Human and Animal Food Operations – East (OHAFOE) Director.
- (7) ORA/OHAFO/Office of Human and Animal Food Operations – West (OHAFOW) Director.

2. Redelegation.

These officials may not further redelegate these authorities.

3. Effective Date.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on 10 February 2020.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	02/10/2020	N/A	CFSAN/OC	Stephen M. Hahn, M.D. Commissioner of Food and Drugs