

SMG 1410.307

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Food and Cosmetics

**Determinations Related to Processes or Treatments Not Meeting
the Requirements of the Federal Food, Drug, and Cosmetic Act**

Effective Date: 2 June 2021

1. Authority Delegated and To Whom Delegated.

A. The officials listed below are authorized to perform all the functions of the Commissioner of Food and Drugs under section 403 (h)(3)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to make determinations that a process or treatment has not been shown to meet the requirements of sections 403(h)(3)(B)(i)(I) through (III) of the FD&C Act:

- (1) Center for Food Safety and Applied Nutrition (CFSAN) Director and Deputy Directors.
- (2) CFSAN/Office of Food Safety (OFS) Director and Deputy Directors.
- (3) CFSAN/OFS/Division of Dairy, Eggs, and Meat Products (DDEMP) Director.
- (4) CFSAN/OFS/Division of Plant Products and Beverages (DPPB) Director.

2. Redelelegation.

These officials may not further redelegate these authorities.

3. Effective Date.

The Acting Commissioner of Food and Drugs approved this delegation, via memorandum, on 2 June 2021.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	09/03/2014	N/A	OFVM/ CFSAN/ OM	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	06/02/2021	N/A	CFSAN/ ORP/ RDS	Janet Woodcock, M.D. Acting Commissioner of Food and Drugs