

SMG 1410.117

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Human Drugs

Notification, Nondistribution, and Recall of Controlled Substances

Effective Date: 17 June 2021

1. Authority Delegated and To Whom Delegated.

A. The officials listed below are authorized to perform all of the functions of the Commissioner of Food and Drugs relating to notification, nondistribution, and recall of controlled substances under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb – 8d) Chapter V, Subchapter E, Section 569D as authorized in The SUPPORT for Patients and Communities Act (P.L. 115-271) Section 3012 of 24 October 2018:

(1) Center for Drug Evaluation and Research (CDER) Director.

2. Redelelegation.

A. The authority to issue an Order pursuant to 21 U.S.C. 360bbb-8d(a)(1) may be redelegated.

B. As provided in 21 U.S.C. 360bbb-8(c), the authority to issue an Order pursuant to 21 U.S.C. 360bbb-8d(a)(3) may not be redelegated.

3. Effective Date.

The Acting Commissioner of Food and Drugs approved this delegation, via memorandum, on 17 June 2021.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	06/17/2021	N/A	CDER/ OM	Janet Woodcock, M.D. Acting Commissioner of Food and Drugs