

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Human Drugs

**Regulation of Certain Nonprescription Drugs That Are
Marketed Without an Approved Drug Application**

Effective Date: 20 September 2021

1. Authority Delegated and To Whom Delegated.

- A. The officials listed below are delegated the authority to perform all the functions of the Commissioner of Food and Drugs as authorized in section 505G; except for the functions under 505G(b)(3), (b)(4)(E), and (b)(4)(F); of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as added to the FDA&C Act by the Coronavirus Aid, Relief, and Economic Security (CARES) Act of 27 March 2020:
- (1) Center for Drug Evaluation and Research (CDER) Director and Deputy Directors.
 - (2) CDER/Office of New Drugs (OND) Director and Deputy Directors.
 - (3) CDER/OND/Office of Nonprescription Drugs (ONPD) Director and Deputy Director.
 - (4) CDER/OND/ONPD/Division of Nonprescription Drugs I (DND I) Director and Deputy Director.
 - (5) CDER/OND/ONPD/Division of Nonprescription Drugs II (DND II) Director and Deputy Director.

2. Limitations

- A. This Delegation of Authority does not include functions reserved to the Secretary of Health and Human Services under section 505G(b)(4)(A) of the FD&C Act.

3. Redelelegation.

- A. These officials may not further redelegate these authorities.

4. Effective Date.

The Acting Commissioner of Food and Drugs approved this delegation, via memorandum, on 20 September 2021.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	09/20/2021	N/A	CDER/ OND/ ONPD	Janet Woodcock, M.D. Commissioner of Food and Drugs