

SMG 1410.101

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Drugs

**Issuance of Notices Implementing the Provisions of the
Drug Amendments of 1962**

Effective Date: 30 March 2026

1. Authority Delegated and To Whom Delegated.

A. The officials listed below are authorized to issue notices and amendments thereto implementing section 107(c)(3) of the Drug Amendments of 1962 (Public Law 87-781) by announcing new or revised efficacy findings on human drugs that are or were subject to the provisions of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355):

- (1) Center Drug Evaluation and Research (CDER) Director and Deputy Directors.
- (2) CDER/Office of Generic Drugs (OGD) Director and Deputy Directors.
- (3) CDER/Office of New Drugs (OND) Director and Deputy Directors.
- (4) CDER/Office of Pharmaceutical Quality (OPQ) Director and Deputy Directors.
- (5) Center for Devices and Radiological Health (CDRH) Director and Deputy Directors.
- (6) CDRH/Office of Product Evaluation and Quality (OPEQ) Director; Deputy Directors; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.

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 30 March 2026.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	04/14/2003	N/A	OA/ OM/ OMP	Mark Barr McClellan, M.D., Ph.D. Commissioner of Food and Drugs

Status	Date Approved	Location of Change History	Contact	Approving Official
Revision	03/30/2026	N/A	CDER/ ORP	Martin A. Makary, M.D., M.P.H. Commissioner of Food and Drugs