

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Tobacco

Issuance of Written Notice Related to Enhanced Civil Money Penalties

Effective Date: 2 June 2025

1. Authority Delegated and To Whom Delegated.

A. The officials listed below are authorized to issue written notice related to enhanced civil money penalties under section 303(f)(9)(B)(i)(II) and (B)(ii)(II) of the Federal Food, Drug, and Cosmetic Act:

- (1) Center for Tobacco Products (CTP) Director and Deputy Director.
- (2) CTP/Office of Compliance and Enforcement (OCE) Director and Deputy Directors.

2. Redelelegation.

These officials may not further redelegate this authority.

3. Effective Date.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on 2 June 2025.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	06/02/2025	N/A	CTP/ OR	Martin A. Makary, M.D., M.P.H. Commissioner of Food and Drugs