



Memorandum

Date: November 4, 2024

To: FDA Dockets Management Staff

From: FDA Regulations Policy and Management Staff

Subject: Prohibition of Sale of Tobacco Products to Persons Younger than 21 Years of Age (Final Rule) [Docket No. FDA-2020-N-1395]

The September 30, 1993, Executive Order (E.O.) 12866 “Regulatory Planning and Review” (as amended by the April 6, 2023, Executive Order 14094 “Modernizing Regulatory Review”) sets forth the principles and requirements for the Federal regulatory process. Under section 6(a)(3)(E) of E.O. 12866, for “significant regulatory actions,” Federal agencies must make certain information available to the public after publication of the regulatory action in the *Federal Register*.

Pursuant to E.O. 12866 for significant regulatory actions, FDA has saved to the Dockets Management Staff’s shared drive the following information:

- 1) A copy of the draft version of the regulatory action as submitted to the Office of Management and Budget’s Office of Information and Regulatory Affairs (OIRA) for review (TAB A);
- 2) The substantive changes between the draft submitted to OIRA for review and the regulatory action subsequently cleared by OIRA are shown in track changes text review¹ (TAB B); and,
- 3) A copy of the final version of the regulatory action as cleared by OIRA (TAB C).

Please disregard any formatting and editorial changes; such changes are considered non-substantive, administrative corrections, or adjustments that do not impact the material content or meaning of the rule and are generally considered inconsequential and without regulatory effect. Such changes originated from FDA.

Please make these materials physically available at FDA Dockets Management and post the information on www.regulations.gov.

Thank you.

¹ Insertions appear as blue with a single underline. Deletions appear as redline with a single strikethrough. Text moved to a new location appears in green with a double underline. Text moved from a location appears in green with a double strikethrough.