



November 7, 2024

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2024-D-3742 for “Enforcement Policy for Required Warnings for Cigarette Packages and Advertisements

Dear FDA Staff:

The Energy Marketers of America (EMA) respectfully file these comments on FDA’s guidance document issued on September 13, 2024 regarding enforcement of the rule requiring graphic warnings for cigarette packages and advertisements. The guidance states that FDA intends to exercise enforcement discretion and generally not enforce requirements of the graphic warnings rule for 15 months after the date of the guidance—i.e., until December 12, 2025—and for an additional 30 days (until January 12, 2026) for products manufactured before December 12, 2025. **Retailers also need regulatory guidance that the FDA make clear that retailers and distributors may sell cigarettes without graphic warnings so long as the cigarettes were validly manufactured by December 12, 2025 and introduced into commerce by January 12, 2026.**

Introduction

EMA is a federation of 49 state and regional trade associations representing energy marketers throughout the United States. EMA member companies supply 80 percent of all finished motor and heating fuel products sold nationwide including gasoline, diesel fuel, heating fuels and biofuels such as renewable diesel and biodiesel. EMA members also own and operate the majority of gas stations nationwide, which are mostly small family-owned and operated businesses. The retail motor fuels market is the most competitive marketplace in the country. Retailers post their prices on big signs where a one-penny difference can decide where customers choose to fill up. Because gasoline retailers operate in such a competitive environment, the higher prices climb, the further margins are squeezed. Gas station retailers are also hurt by high fuel prices.

In addition, the majority of the major integrated oil companies have removed themselves from the retail gasoline business. Of the 150,000 U.S. retail gasoline locations, the vast majority are owned by independent motor fuel marketing businesses. While those small businesses may sell a particular brand of gasoline, they do not share in any of the profits (or losses) generated by refiners and oil companies. As such, EMA represents many of the tens of thousands of small businesses nationwide that, in addition to providing fuel, include convenience store outlets that derive a substantial percentage of their revenues from tobacco products.

Sell Through Period of Manufacturers and Retailers

The federal statute and the graphic warnings rule contemplate that retailers and distributors will have a sell-through period for cigarettes that lack graphic warnings, so long as those cigarettes were manufactured before the effective date and introduced into commerce within 30 days after the effective date. The statute states: “The effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with paragraph (2)(A)(ii).” 21 U.S.C. § 387k(b)(3). This language is most naturally read to mean that the effective date pertains only to the date when the

cigarette is manufactured. And while the statute expressly prohibits manufacturers from introducing cigarettes without graphic warnings into interstate commerce starting 30 days after the effective date, the statute does not expressly place any limit on sales by retailers and distributors of cigarettes that were manufactured before the effective date and introduced into commerce within 30 days after the effective date. The FDA’s small entity compliance guide, which was updated shortly after FDA issued the Guidance, supports this interpretation: “Distributors and retailers may continue to sell and distribute the cigarette product after the effective date of the final rule, but only if the product was manufactured before the effective date, and introduced into domestic commerce by the manufacturer within 30 days from the effective date of the rule.”

A sell-through period for retailers and distributors is important given the real-world implications of stock management and other practical considerations. Limiting the sell-through period for retailers and distributors to 30 days would make it extremely hard for them to sell their stock of cigarettes without graphic warnings in time to comply with the rule. Because manufacturers would be entitled to the 30-day sell-through period, they could continue introducing cigarettes without graphic warnings into interstate commerce until the end of that period. The 30-day sell-through limit on manufacturers will ensure that cigarettes without graphic warnings largely disappear from the market in short order. Thus, there is no compelling practical reason to impose the same sell-through limit on retailers and distributors.

The current Guidance document does not expressly address the sell-through period for retailers and distributors. Instead, as to sell-through issues, the Guidance simply says that FDA does not intend to enforce the graphic warnings rule during the 30-day manufacturer sell-through period. But the Guidance does state that FDA’s exercise of enforcement discretion is meant to mirror the effective date as set out in the statute and the rule. And as explained above, the statute contemplates that retailers and distributors may sell through cigarettes without the graphic warnings so long as the cigarettes were validly manufactured and introduced into commerce.

Therefore, EMA urges the FDA to revise the Guidance to make clear that retailers and distributors may sell cigarettes without graphic warnings so long as the cigarettes were validly manufactured by December 12, 2025 and introduced into commerce by January 12, 2026. FDA already provided such clarity in the context of the Deeming Rule. FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements (Revised), Small Entity Compliance Guide at 29-30 (March 2023). It should do so again here.

Sincerely,

A handwritten signature in black ink, appearing to read "Rob Underwood", enclosed in a thin black rectangular border.

Rob Underwood
President
Energy Marketers of America