



## Proceed at Your Own Risk: FDA Issues Final Rule Requiring New Warnings for Cigarette Packages and Advertisements

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In a world where the Coronavirus has taken over all of our day-to-day lives, other parts of the Food and Drug Administration continue to focus on initiatives that “promote greater public understanding [of the] negative health consequences of smoking.”<sup>1</sup> Almost 11 years since the passing of the Family Smoking Prevention and Tobacco Control Act, on March 17, 2020, FDA issued a Final Rule that requires new health warnings on cigarette packages and advertisements.<sup>2</sup> According to the agency, “smoking remains the leading cause of preventable disease and death in the United States and is responsible for more than 480,000 deaths per year.” In issuing the Final Rule, FDA determined that the public still holds many misconceptions about the health risks of smoking, and that “textual warning statements focused on less-known health consequences of smoking paired with concordant color graphics will promote greater public understanding of the risks associated with cigarette smoking.” To that end, the Final Rule specifies “11 new textual warning label statements and accompanying color graphics.” The new requirements will go into effect on June 18, 2021.

FDA also issued a companion guidance document entitled, “Required Warnings for Cigarette Packages and Advertisements, Small Entity Compliance Guide,” to help small business understand and comply with the new Final Rule.<sup>3</sup>

### Highlights of the Final Rule

- The Final Rule applies to manufacturers, distributors, and retailers of cigarettes.
- Each cigarette package and advertisement must bear one of the new 11 required warnings.
- The warnings must be **randomly and equally displayed and distributed** and manufacturers, distributors, or retailers are required to submit a plan to FDA for the random and equal distribution, as well as the **quarterly rotation in advertisements** for approval by FDA. This means that manufacturers must create a plan to ensure that the all 11 warnings are:
  - Randomly displayed during each 12-month period on each brand of the product;
  - Displayed on each brand of the product in as equal a number of times as possible during each 12-month period;
  - Randomly distributed in all areas of the United States in which the product is marketed; and
  - Displayed at the same time (i.e., all 11 warnings must appear on each brand or set of brands for the product at the same time).
- The required warnings must be placed in a quarterly rotation, in alternating sequence, in advertisements distributed for each cigarette brand.

<sup>1</sup> See Message from the FDA’s Office of Global Policy and Strategy, available here <http://s2027422842.t.en25.com/e/es?s=2027422842&e=312629&elqTrackId=376c7bc788024cd5a73d955f2e3dcbdc&elq=bd1fac26f458421893146a68b4ff7453&elqaid=11661&elqat=1>.

<sup>2</sup> See Final Rule entitled, “Tobacco Products; Required Warnings for Packages and Advertisements, available at <https://www.federalregister.gov/documents/2020/03/18/2020-05223/tobacco-products-required-warnings-for-cigarette-packages-and-advertisements>.

<sup>3</sup> A copy of the guidance document can be found here: <https://www.fda.gov/media/136185/download>.

- FDA is encouraging manufacturers to reach out to the agency to discuss their approach for meeting the “random and equal” requirements.<sup>4</sup>
- Each tobacco product manufacturer must maintain a copy of the FDA-approved plan and make the plan available for inspection and copying by officers and employees of the FDA.
- The new cigarette health warnings must appear prominently on packages and advertisements, occupying the top 50 percent of the area of the front and rear panels of cigarette packages and at least 20 percent of the area at the top of cigarette advertisements.<sup>5</sup>
- The 11 new textual warnings are as follows:
  - a. WARNING: Tobacco smoke can harm your children.
  - b. WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
  - c. WARNING: Smoking causes type 2 diabetes, which raises blood sugar.
  - d. WARNING: Smoking reduces blood flow to the limbs, which can require amputation.
  - e. WARNING: Smoking causes cataracts, which can lead to blindness.
  - f. WARNING: Smoking causes bladder cancer, which can lead to bloody urine.
  - g. WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.
  - h. WARNING: Smoking causes head and neck cancer.
  - i. WARNING: Smoking can cause heart disease and strokes by clogging arteries.
  - j. WARNING: Smoking during pregnancy stunts fetal growth.
  - k. WARNING: Smoking causes COPD, a lung disease that can be fatal.

## AGG Observations

- Given the amount of guidance that FDA is providing to manufacturers, retailers, and distributors of cigarette products, it is unlikely that FDA will extend the effective date of June 18, 2021. As such, entities should start implementing the requirements as soon as possible.
- A cigarette will be deemed misbranded, a prohibited act, if it does not bear one of the required warnings, or if its advertisement does not bear one of the required warnings.
- Failure to comply with the Final Rule can result in warning letters, criminal and civil money penalties, injunctions, seizures, and no-tobacco-sale orders.
- Retailers should be aware that the Final Rule also applies to them, and they can face enforcement action, unless certain requirements are met. FDA is not shy of taking such actions. FDA issued more than 14,000 Warning Letters during Fiscal Year 2019 against retailers across the country.
- According to FDA, it may take up to 6 months for it to review and approve the required plans for the random and equal display and distribution of the warnings and the quarterly rotation of required warnings on cigarette advertising. While June 18, 2021 appears to be far away at this point, companies should ensure that they are diligently working to put together these submissions. As per FDA small business guidance, if there is a higher volume of submissions received by FDA than currently expected, FDA intends to ensure that any entities that submit an “adequate plan” within five months from the publication of the Final Rule (i.e., August 2020) are not delayed or prevented from distributing cigarette packages or advertising the products due to the Agency’s not having approved their plans by the effective date of the rule.
- It is unclear how the current situation with the Coronavirus will affect FDA’s ability to review and approve plans in a timely manner, so it is even more critical to submit any plans for approval as early as possible.

<sup>4</sup> The agency also issued a guidance document on March 19, 2020, with information and recommendations for preparing the required plans. The guidance for industry entitled, “Submission of Plans for Cigarette Packages and Cigarette Advertisements” is available at <https://www.fda.gov/media/133839/download>

<sup>5</sup> Copies of the graphics and technical specifications may be found here: <https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-health-warning-design-files-and-technical-specifications>

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