

NATO News

Critical News for Members on Tobacco Legislation, Litigation and Regulations

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Update: The FDA's Proposed Menthol Cigarette and Flavored Cigar Bans

On April 28, 2022, the Food and Drug Administration published two new proposed regulations. These regulations are known as product standards. A product standard is the power that Congress gave to the FDA to reduce or eliminate an ingredient in a tobacco product or a constituent in tobacco smoke.

One of the proposed regulations would prohibit menthol as a flavor in cigarettes, in roll-your-own cigarette tobacco, and in heated tobacco products. The second regulation would prohibit any flavors in cigars.

As a part of the federal regulatory process, federal law requires that an agency must request comments from the public about proposed regulations. The FDA received more than 175,000 comments on the menthol cigarette ban and almost 72,000 on the flavored cigar ban by the August 2, 2022 submission deadline.

In response to this significant number of comments, the FDA issued an announcement that it “will need ample time to comprehensively review and analyze all of the comments.” Since the FDA announced it will need “ample” time to read all of the comments, it could take 9 to 12 months or possibly longer for the agency to read through the comments on the menthol ban and flavored cigar ban. Then, the FDA will decide whether to draft any changes to the proposed regulations and, if it does so, that may take several months.

After any changes are made, the FDA will need to send the final proposed regulations to the White House Office of Management and Budget (OMB) for its final review and decision on whether the FDA can proceed with implementing the regulations. During this time, the OMB may meet with members of the public for their input on the final regulations. This OMB review and meeting process may take up to two months or longer.

Also, in the proposed regulations, the FDA asked for public feedback on making the effective date of the regulations two years after the final regulations are published instead of the usual one year time period before the regulation takes effect. Some manufacturers recommended in their comments that the FDA consider making the regulations effective six years after the final regulations are published. Then, there is also the possibility that lawsuits could be brought against the FDA regarding the proposed regulations, which may further delay an effective date.

Based on the estimated time periods for the FDA to review the public comments, make changes to the regulations, and obtain OMB final approval, it could take almost a year and a half before the final regulations would be published. Then, when publishing the final regulations, the FDA will need to determine on what date the regulations will go into effect (e.g., one year, two years, or some other length of time). When adding up all of these time periods, the estimated time when the menthol cigarette ban and flavored cigar ban may go into effect is approximately 2 ½ years to possibly 3 ½ years from now, not including an extended effective date beyond two years from the date of publication or a postponed effective date due to potential litigation.