NATO News

Critical News for Members on Tobacco Legislation, Litigation and Regulations

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Special Report

FDA Announces Plan to Propose Ban Menthol in Cigarettes and Characterizing Flavors in Cigars

Today, the U.S. Food and Drug Administration issued an announcement that the agency plans to propose new rules to adopt product standards to remove menthol from cigarettes and remove characterizing flavor additives from cigars. In its announcement, the FDA states that the new proposed rules will be issued "within the next year." A copy of the full FDA announcement accompanies this bulletin and below is a summary of the key aspects of this announcement.

Product Standards: In the Family Smoking Prevention and Tobacco Control Act, Congress authorized the FDA to adopt what is known as a "product standard." A product standard is a rule that the FDA can propose and adopt to reduce or eliminate constituents in a tobacco product or in tobacco smoke. A flavor is a constituent of a tobacco product and the product standards that the FDA is now planning to propose would eliminate menthol as a flavor constituent in cigarettes and all flavors that are constituents in cigars. This means that no Congressional action is required for the FDA to continue with the rulemaking process and propose and adopt these two product standard rules.

Rulemaking Process: Under federal law, each federal agency that plans to adopt a new rule must follow a nine-step process which is detailed in the accompanying "The Reg Map" chart. This nine-step process includes the following steps:

> **Step One-Initiating Events**: The agency decides whether to pursue a new rule or is required to do so due to statutory mandates, recommendations from other agencies, a lawsuit ruling, petitions, or as recommended by the Federal Office of Management and Budget (OMB).
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> **Step Two-Determining Whether a Rule is Needed:** The agency must follow Administrative Procedures Act requirements to determine whether a new rule is needed.
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> **Step Three-Preparation of Proposed Rule:** The agency drafts a new proposed rule.

Step Four-OMB Review of Proposed Rule: The OMB reviews those proposed rules which may have a significant impact on the economy or budget of the United States.

Step Five-Publication of Proposed Rule: The agency publishes a complete copy of the proposed rule in the Federal Register.

Step Six-Public Comments: The public is provided a time period to submit comments to an agency about the proposed rule.

Step Seven-Preparation of Final Rule: After reviewing all of the public comments submitted, the agency decides whether any changes or deletions are to be made to the proposed rule and drafts a final rule.

Step Eight-OMB Review of Final Rule: The OMB conducts a review of the final rule.

Step Nine-Publication of Final Rule: The agency publishes the final rule in the Federal Register and sets a date for the rule to go into effect.

In the case of the FDA's announcement today, and according to Step One above, the agency agreed to accept a citizens' petition which was filed with the FDA in 2013 and called for a rule to ban the use of menthol in cigarettes.

Multi-Year Process: A rulemaking process is generally a multi-year event. As referenced above, the FDA announcement states that the agency plans to issue the two proposed product standard rules "within the next year." Doing so would encompass Steps Three, Four and Five of the rulemaking process since the agency needs to draft the product standard rules, submit the proposed rules to the OMB for review, and then publish the proposed rules for public comment. The length of time that an agency allows for public comment may vary and the public can also request an extension of the comment period to allow more time to compile and submit comments. It is up to the discretion of the agency whether an extension of time is approved.

Then, the agency is required to review every comment submitted on a proposed rule which will take time and this review may lead to amendments to the rule. Additional time will then be taken up by an OMB review of the final rule.

Enforcement of Final Rule: In its announcement, the FDA clarifies that if the final rules are implemented, then the agency will enforce the rule against manufacturers, distributors, wholesalers, importers, and retailers. The FDA provides an acknowledgement that it "cannot and will not enforce against individual consumer possession or use of menthol cigarettes or any tobacco product" and that the agency "will work to make sure that any unlawful tobacco products do not make their way onto the market."

Monitoring of Rulemaking Process: NATO will monitor this rulemaking process closely and update NATO members at the various stages of the rulemaking process including how to submit comments to the FDA.