May 13, 2020

Categories:

Coronavirus Response Team
Publications

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FDA Deeming Regulations Deadline for Tobacco Industry Extended Again

Tobacco product manufacturers can now take a temporary sigh of relief after Judge Paul Grimm of the Maryland U.S. District Court recently granted the FDA's motion to extend the upcoming May 12, 2020, deadline for filing premarket tobacco applications (PTMA) pursuant to the FDA's Deeming Regulations for new tobacco products, giving the industry another 120 days until September 9, 2020, to make such submissions.

Why is this important? Tobacco manufacturers now have additional time to submit substantial equivalence (SE) reports, and other PMTAs, to the FDA as many were running out of time or did not have the resources to timely complete these submissions, and since many in the cigar and e-cigarette industry are continuing to wait for guidance from the FDA concerning scientific and other data needed for their SE reports.

How Did We Get Here?

On August 8, 2016, the FDA's Deeming Regulations went into effect, and for the first time, the FDA formally regulated all tobacco products, including cigars, pipe tobacco, e-cigarettes, and other forms of tobacco products not previously under its purview.

As a result of the Deeming Regulations, there were several new restrictions and requirements for tobacco product manufacturers and retailers, the most important being the filing of a PMTA to get approval for certain tobacco products to continue to be sold in the U.S. The most realistic pathway to receive such approval is the filing of a SE Report to show that a "new" tobacco product has similar characteristics to a "grandfathered" (predicate) tobacco product (i.e., one on the market prior to February 15, 2007), or has different characteristics, but doesn't raise any new questions of public health, which, if approved by the FDA, would allow such products to continue to be sold.

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In June 2019, Judge Grimm ruled against the FDA's prior extension of the PMTA deadlines to 2021, and instead set a May 12, 2020, deadline for companies to make these submissions to obtain approval of all new tobacco products, and continue to sell these products while such PMTAs were being reviewed by the FDA in a case currently pending before the Fourth Circuit, American Academy of Pediatrics, et al. v. FDA, et al., No. 8:18-cv-00883 (D. Md.), *on appeal*, Nos. 19-2130, 19-2132, 19-2198, 19-2242 (4th Cir.)

Many in the tobacco industry reached out to the FDA last month to push back the May 12, 2020, deadline due to the shutdown of the economy and remote working resulting from the COVID-19 pandemic. This includes a joint petition by the Premium Cigar Association and the Cigar Rights of America (requesting a 6-month extension for SE reports), and as a result, the FDA filed a motion with Judge Grimm on March 30, 2020, requesting the 120-day extension, and also notifying the Fourth Circuit.

The plaintiffs in the above-action, a coalition of public health and anti-tobacco advocacy groups which sued to require the FDA to adhere to the May 12 deadline, did not formally oppose the motion but asked that any extension not lead to further extensions. While Judge Grimm indicated on April 3, 2020, that he would grant the extension if remanded back to him, it wasn't until April 23, 2020, that the deadline was formally extended.

Delay Especially Needed for Those Awaiting More FDA Guidance on PMTAs

While the extension is important to manufacturers of all new tobacco products, the news was especially critical to those in the premium cigar and e-cigarette industry. These manufacturers continue to wait for the FDA to issue critical guidance on the data they must provide regarding the harmful and potentially harmful constituents (HPHCs) for new tobacco products. This is another element that could cause further delays or uncertainty for the tobacco industry until that guidance is finally issued. Without it, it would be difficult to submit a complete SE Report for such products, if necessary.

Will it be Extended Further?

Additional extensions may be possible due to several lawsuits currently ongoing. For example, in addition to the American Academy of Pediatrics case at the Fourth Circuit Court of Appeals, the main lawsuit for the cigar industry filed in 2016 against the FDA by three cigar trade groups, Cigar Association of America e al. v. the United States Food and Drug Administration et al., is still raging on before the U.S. District Court of the District of Columbia, and has also been joined with another suit out of Texas, En Fuego Tobacco Shop LLC, et al. v. U.S. Food and Drug Administration, et al. As it has for the past few years, it will likely go down to the wire in September to see if the PMTA deadlines will be extended again due to COVID-19, a victory or agreement in one of the lawsuits, or some legislative or regulatory action(s) which cause further delays.

Closing Thoughts

While this is welcomed news for most in the industry, there is still a great deal of uncertainty regarding the FDA Deeming Rule deadlines and processes. To the extent a company can continue to move forward on planned SE reports or other pathway submissions to the FDA, it would be wise to continue to do so during the next few months in case September 9, 2020, really is the final date for these submissions in order to continue to market and sell your new tobacco products.

For more information, please contact Daniel Mudd, Member of Frost Brown Todd's Tax Law Practice Group, and a Leader of its Consumable Goods Industry Team which oversees all of the Firm's tobacco, alcohol, hemp, food and beverage manufacturing clients.

To provide guidance and support to clients as this global public-health crisis unfolds, Frost Brown Todd has created a Coronavirus Response Team. Our attorneys are on hand to answer your questions and provide guidance on how to proactively prepare for and manage any coronavirus-related threats to your business operations and workforce.

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