EXHIBIT J

Perspective: FDA's Preparations for the September 9 Submissi

By Mitch Zeller, Director of the FDA's Center for Tobacco Products (CTP)
August 31, 2020

On Sept. 9, premarket review applications for many new tobacco products, including e-cigarettes, certa products, currently on the market are due to FDA for review. FDA staff have been working tirelessly on p challenge in an efficient, reliable and transparent manner.

The Deeming Rule and FDA's Premarket Review Requirement for Deemed Tobacco Products

Prior to Aug. 8, 2016, e-cigarettes, cigars and hookah products were not regulated by FDA. That's because th authority from Congress in 2009 only covered cigarettes, smokeless tobacco, cigarette tobacco, and roll-your

That all changed with FDA's historic "Deeming Rule" that helps implement the Tobacco Control Act and allo public health and protect future generations from the dangers of tobacco use. On Aug. 8, 2016, when the dee many of the regulatory and statutory requirements that had been in place for manufacturers of cigarettes, sm cigarette tobacco, and roll-your-own tobacco since 2009, became applicable to e-cigarettes and all other elec systems (ENDS), cigars, pipe tobacco, nicotine gels, hookah tobacco, and any future tobacco products.

Before the deeming rule, there were no federal protections on, among other things, retailers selling these tob The deeming rule changed that and its continued implementation has allowed FDA to make great strides in through tobacco regulation—for example, manufacturers of these tobacco products must register their estab products with FDA, products may not be marketed with direct or indirect claims of reduced risk unless subs they receive FDA authorization to do so, and retailers are prohibited from selling these tobacco products to y

Importantly deemed tobacco products are now subject to the requirements in the Tobacco Control Act that a cigarettes and smokeless tobacco products. This includes the requirement that a "new tobacco product" (/tob

FDA prior to marketing.

For deemed products that met the definition of a new tobacco product and were on the market as of Aug. 8, rule took effect), FDA issued a compliance policy; this, in effect, provided more time for manufacturers of th their applications for authorization. The deadline for the submission of applications for these products is no result of a court order (and a subsequent extension due to the unique circumstances of the COVID-19 pande deemed new tobacco products on the market at that time are **due to FDA by Sept. 9, 2020 [1].** The court o one-year period during which products with timely filed applications might remain on the market pending F

Since the deeming rule took effect, FDA has been taking measures to prepare for the large volume of applica anticipates receiving, particularly from manufacturers of e-liquids, e-cigarettes and other ENDS products.

Expectations for Applications Coming in by Sept. 9

All new tobacco products are required to obtain premarket authorization through one of three pathways: (/t products/products-guidance-regulations/market-and-distribute-tobacco-product) Premarket Tobacco Prod (PMTA), Substantial Equivalence (SE) Reports, or Requests for Exemption from Demonstrating Substantial Those deemed new tobacco products still on the market that do not have premarket applications submitted l subject to FDA compliance and enforcement actions.

However, there may be some deemed tobacco products that are eligible for "grandfathered status" because t marketed in the United States as of Feb. 15, 2007. These deemed tobacco products are not "new tobacco pro not need to submit premarket applications (unless the products were since modified). We expect that many and pipe tobacco products may fall in this category, and we encourage manufacturers to request a determina (/tobacco-products/market-and-distribute-tobacco-product/grandfathered-tobacco-products)on their prod status. For deemed tobacco products that are not eligible for grandfathered status, (/tobacco-products/mark tobacco-product/grandfathered-tobacco-products) manufacturers may decide that their product is sufficien previously authorized or grandfathered product and find that the SE or EX REQ pathway is the most approp applications.

To date, no ENDS product has received marketing authorization from the FDA and FDA has not issued a gra determination for an ENDS product. All premarket applications for ENDS products accepted by the FDA hav through the PMTA pathway, and we expect most applications for ENDS products submitted on or before Sep through the PMTA pathway.

Although we do not know how many applications will be submitted by the September deadline, we do know million deemed products listed with FDA.
(https://ctpocerl.fda.gov/rlapp/home.html;jsessionid=6N0uTk7SupBTUcBdML7O5bwgjnNt14sWQ60uOR Even if applications are submitted for only a portion of those products, the likelihood of FDA reviewing all o during the one-year review period is low, given that this would be an unprecedented number of applications

magnitude greater than anything the Agency has experienced. However, FDA has been planning and prepari expected influx of applications for years. Our preparations are intended to help ensure that our approach to public health and is fair, consistent, efficient, and as transparent as possible.

We have been encouraging companies to submit their applications as early as possible. To date, FDA has rec around 2,000 deemed products – of which around 40 percent have already been resolved.

Preparations to Receive Premarket Review Applications

FDA has been working tirelessly to ensure that we are as prepared as possible to receive, process, and review timely manner. To help accomplish this, we have been laying the groundwork for many years.

Since Congress authorized FDA to regulate tobacco products in 2009, CTP's staff has increased from just a h today. During that time, we have built product review expertise and refined our premarket review processes, capabilities, issued rules and guidances, met with stakeholders to get a better understanding of tobacco prod needs for information about the process, invested in tobacco product research, and provided resources to he submit premarket applications.

BUILDING EXPERTISE AND REFINING THE PREMARKET REVIEW PROCESSES

Although the applications received in response to the Sept. 9 deadline will generally be for deemed products successfully conducting premarket review of cigarettes, smokeless tobacco and roll-your-own tobacco for ma we have received over 600 PMTAs, more than 7,700 SE Reports and over 800 EX REQs—and have closed ou these applications. Shaped by the experiences, challenges and lessons learned over the last decade, we have refinements to our processes to ensure that we are able to receive and review these applications properly and

We've also greatly increased the number of staff that we have conducting premarket reviews. Since 2011, CT Science has increased ten-fold, from around 40 to over 400 full-time employees today – and the majority of of their time on product review. CTP continues to hire and train more staff to conduct product review in anti applications. These improvements put us in a much better position to handle the applications than we were received a large influx of over 3,600 SE Reports within a week of the "provisional SE" application deadline [2]

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