Implementation of FDA Deeming Regulations Delayed

On July 28th, the Food and Drug Administration (FDA) announced that it was delaying the implementation of portions of its May 2016 regulations which broadened their authority to include products such as electronic cigarettes, cigars, little cigars, and hookah tobacco. In addition to requiring those products adhere to the FDA’s regulatory process, other key provisions included those which gave the agency the ability to set minimum age to purchase requirements and the ability to require warning labels on the newly-deemed products. Previously, the FDA exerted authority only over cigarettes and smokeless tobacco.

The recently announced delays in implementation will extend the deadlines by which manufacturers must submit applications for FDA review for newly-deemed products. Products which were on the market prior to February 15, 2007 are grandfathered and do not have to seek FDA authorization. Products which were introduced to the market between that date and August 8, 2016 will be required to seek authorization according to the newly-updated timeline. Under this new timeline, combustible products, such as little cigars and hookah, have until August 2021 to submit their applications. Non-combustible products, such as electronic cigarettes, will have until August 2022. Prior to these changes, the deadlines were 2017 and 2018, respectively. Products introduced after August 8, 2016 are required to seek authorization prior to being sold.

To read the American Lung Association’s full press release concerning these implementation delays, please click HERE.

If you have questions about this analysis, please contact Diana Douglas (diana.douglas@lung.org).