A Whole New World:

Surviving the FDA's Tobacco Requirements

While the future for businesses affected by FDA tobacco regulations has been painted as bleak for all but the largest corporations, in truth survival is within the reach of many businesses regardless of size—if proper planning is adopted early. **>BY BRYAN M. HAYNES**

Less than a year ago, the Food and Drug Administration assumed jurisdiction over segments of the tobacco industry—electronic cigarettes, cigars, hookah tobacco, and pipe tobacco, to name a few—that previously were unaccustomed to the same requirements governing the cigarette and smokeless tobacco categories. Once all of the FDA's requirements take effect (assuming they do), this will require companies to change the way they do business in several fundamental ways.

Does this mean that the end is near for all but the most well-capitalized companies? Of course no one can predict the future, but I can tell you that it is possible to survive in this regulatory environment; it will, however, be very challenging and require an institutional commitment to regulatory requirements. Having advised companies regarding the FDA's tobacco requirements for almost ten years, I offer a few basic tips for orienting your business toward these new requirements.

UNDERSTANDING REQUIREMENTS, DEVELOPING A COMPLIANCE PLAN

This point may seem self-evident, but in order to survive in this environment, you first need to understand the FDA's requirements and how they apply to our business. In general, there is a hierarchy of FDA requirements. First is the 2009 Family Smoking Prevention and Tobacco Control Act, or TCA. The TCA is a law passed by Congress takes precedence over all other requirements. Next are the FDA's regulations, such as the Deeming Regulations that took effect in August 2016. Finally, there are FDA guidance documents. These guidance documents do not have the force of law, and it can therefore be a mistake to treat them as a definitive and binding statement of the agency's position on any issue. Guidance documents can, however, be a useful starting point for understanding the FDA's thinking on a particular topic.

There are a variety of resources for understanding the FDA's requirements, not the least of which are certain resources on the agency's own website. Membership organizations such as the Tobacco Merchants Association and the Food and Drug Law Institute offer conferences and publications related to the FDA's tobacco requirements. I also suggest that you work with an individual experienced with the FDA's tobacco requirements who can provide practical advice tailored to your company's needs.

Once you understand the FDA's requirements, you need to develop a plan for compliance. Instead of simply meeting each deadline as they arise, I suggest planning well in advance for all requirements, developing a plan for your overall strategy, and then applying that plan to each requirement. As a former car racer, I liken this strategy to an endurance race. In order to win, you need to have a strategy for the entire race. Focusing only on the first few laps will likely leave you ill-prepared for the remainder of the race. Similarly, focusing only on the end of the race will likely leave you well behind the leaders at the finish. The only way to prevail is to consider the entire race before you start, and develop a well-organized plan to both finish and prevail.

DON'T PROCRASTINATE

A corollary to my point about advance planning is that you should not procrastinate. I certainly recognize that the current regulatory environment is dynamic, and could change significantly depending on decisions made by the Trump administration or Congress in the coming months or years. So when I recommend against procrastinating, I am not suggesting that you prepare and file your submissions months in advance. But you should be thinking about how you will comply

months or years in advance, and slowly build your submissions well in advance of the FDA's deadlines.

Take for example, the FDA's premarket review submissions, which will be due in May 2018 or November 2018, depending on the type of submission. That may seem like a long way off, but it is not. These submissions can take a very long time to compile, and require advance planning and often substantial outside expertise. If you wait until the last minute, I can virtually guarantee that your submission will not meet even the FDA's most basic requirements.

Part of the reason I counsel against procrastination is that there exist limited outside resources that may be required to fulfill the FDA's requirements. Take, for example, analytical testing laboratories that test smoke and vapor chemistry. This testing can be required for the premarket review process, and there is mandatory testing for harmful and potentially harmful constituents due in 2019. It appears that there may be insufficient capacity of qualified laboratories to meet expected demand, and I can guarantee that there will be insufficient capacity if you attempt to begin your testing program shortly before the relevant deadlines.

ENGAGE WITH POLICYMAKERS AND THE REGULATORS

The dynamic regulatory environment presents numerous opportunities to moderate and/or eliminate certain FDA requirements. There are credible efforts underway in Congress that would exempt entire categories of products from FDA regulations and/or mitigate the more onerous requirements, such as premarket review. FDA leadership changes under the new administration also could present opportunities to mitigate the impact of requirements that were driven by the Obama administration.

While one should be prepared for the worst-case scenario (no change to the current regulations), your regulatory strategy should be informed by an understanding of the likelihood for changes to the current requirements. That is why it is important to stay abreast of these efforts.

I also suggest that you actively participate in these efforts, both financially and with your own time. A credible lobbying effort takes both substantial financial resources and a well-organized coalition of industry interests. To the extent you are not participating in these efforts, stop sitting on the sidelines and get engaged!

AN INSTITUTIONAL COMMITMENT

At bottom, compliance with FDA regulations requires an institutional commitment to compliance. In my experience, the single most important factor for success is having an employee with the appropriate level of authority, responsibility, commitment, drive, and knowledge, whose sole or primary function is FDA compliance. There is only so much that outside consultants can do to assist, and without the right information and structure from within the company, your outside consultants' time will not be productively spent.

THE FUTURE MAY NOT BE AS BLEAK AS YOU THINK

Having represented tobacco companies, both large and small, since the TCA passed in 2009, I can tell you that the future may not be as bleak as you think. To be sure, FDA regulations represent a substantial burden, both in terms of time and expense. But with a well-thought-out strategy and perseverance (and perhaps even a little luck), it is possible to defy the odds and survive.

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FDA DEEMING REGULATION RESOURCES

U.S. Food & Drug Administation (FDA) ..... www.fda.gov/TobaccoProducts

What better place to start than at the source of the regulations, the FDA's own website which in addition to providing copies all of the actual regulations provides the agency's important guidance documents as well as dedicated areas for small businesses, manufacturers, and retailers. Visitors can also sign up for email alerts direct from FDA.

Tobacco Merchants Association (TMA) ..... www.tma.org

Founded in 1915 to manage vital information about the worldwide tobacco (and now vapor) industries, TMA's member-access website is the industry's state-of-the-art information portal. Users of TMA information come from companies in most sectors of the tobacco industry including suppliers and allied industries. In addition, the association's annual conference in May features several days of educational sessions and addresses by industry stakeholders addressing the critical issues facing the tobacco and vapor industries.

Food and Drug Law Institute (FDLI) ..... https://www.fdli.org

The Food and Drug Law Institute, founded in 1949, is a nonprofit membership organization that offers education, training, publications, and professional engagement opportunities in the field of food and drug law. As a neutral convener, FDLI provides a venue for stakeholders to inform innovative public policy, law, and regulation. FDLI's scope covers all industries regulated by the U.S. Food and Drug Administration (FDA) and related agencies and authorities in the U.S. and globally, including tobacco products. It also publishes books as essential references on key practice topics, such as "Tobacco and Nicotine Delivery: Regulation and Compliance, 2nd Edition," $349, a 468-page softbound book edited by Azim Chowdhury and J. Ben Haas that provides a comprehensive guide to the legal landscape that is actively shaping the tobacco industry. —Editor