SMOKESHOP

THE INDUSTRY AUTHORITY ON TOBACCO RETAILING

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INNOVATIVE CIGAR RETAILING

CIVIL CIGAR LOUNGE

A Washington, D.C. Drinking, Eating, & Smoking Destination

> Premium Cigars Target New Channels
> Dunhill Cigars Restore their Luster
> Litto Gomez Q&A, La Flor Dominicana

Left: Startup cigarette maker Hestia Tobacco was told that an FDA decision on its request to sell a new brand of all-natural cigarettes could take years. After two years attempting to provide FDA with required information, Hestia gave up, and will launch Hestia little cigars in April 2013 instead.

The Big Chill

The FDA's new tobacco product authority is a significant barrier to product changes, market entry, and innovation. Of the approximately 3,500 "substantially equivalent" product applications submitted to the agency since 2009, the FDA has issued exactly zero rulings.

>BY TROUTMAN SANDERS TOBACCO TEAM

In recent months, the Food and Drug Administration (FDA) has come under increased scrutiny for its evaluation of so-called "new tobacco products." Although FDA must pre-approve any such products that are introduced after March 2011, FDA has not acted on any of these new product applications, instead burying the applications under a mountain of bureaucracy. The result for the industry is a significant barrier to even minute changes in products, such as changing the paper ink on a cigarette, to new companies seeking to enter the cigarette market and to existing companies seeking to introduce innovative new products.

STATUTORY BACKGROUND

As most in the industry know, in 2009 Congress gave FDA authority under the Family Smoking Prevention and Tobacco Control Act to regulate cigarettes, roll-your-own tobacco and smokeless tobacco. Under Section 910 of the Tobacco Control Act, a "new tobacco product" is defined as one that was not commercially marketed in the United States as of February 15, 2007, or that has changed in any way since February 15, 2007. In general, new tobacco products cannot be commercially marketed without an order from FDA.

There was a limited window for new tobacco products that were commercially marketed in the United States before March 22, 2011, so long as the manufacturer submitted a report before March 22, 2011 describing how the new product is "substantially equivalent" to a product commercially marketed before February 15, 2007. Products that fall within this limited window are known as "provisional products." Products commercially marketed as of February 15, 2007 are known as "grandfathered products" or "predicate products."

In order to show that the products are "substantially equivalent," the manufacturer must demonstrate that there are no differences between the two products, or that any differences between the products do not raise different public health questions. In any event, if the manufacturer submitted the required report, the provisional product may be marketed without FDA approval unless and until FDA issues an order indicating that the provisional product can no longer be sold.

As noted above, products that are first commercially marketed in the United States after March 22, 2011 must receive FDA pre-approval. There are three pathways to FDA approval of these products. First, the manufacturer can submit a report showing that the new product is substantially equivalent to a grandfathered product. This report must be submitted at least 90 days before introducing the product to market. This process was intended to be the most streamlined and simplest to satisfy.

Second, the manufacturer can obtain an exemption from the substantial equivalence report by showing that the new product has been modified by adding or deleting a tobacco additive, or by increasing or decreasing the quantity of an additive, that the modification is a minor one, and that permitting the new product is appropriate for the protection of public health.

Third, the manufacturer can submit a more detailed report regarding the product's health risks, components, additives and manufacturing process, and FDA must find that marketing the product is appropriate for the protection of public health. For this more complicated and cumbersome process, FDA must act on reports within 180 days.

New tobacco products that are sold without the required FDA order are deemed to be adulterated under Section 902 of the Tobacco Control Act and can-

not be legally manufactured or sold. Sales of adulterated tobacco products can be penalized by up to one year imprisonment and up to a $1,000 fine, as well as a court injunction. Adulterated tobacco products also can be confiscated by the government.

or to change existing products, are in a much more difficult position. Again, those products require pre-approval before they can be sold, and FDA apparently has not acted on any of those applications, some of which have been pending for almost two years, and 90 percent of which have been pending for more than a year.

>If a manufacturer wanted to market "Brand A" cigarette as "Brand B," without changing the cigarette in any way other than the name, FDA takes the position that this is a new tobacco product requiring FDA approval.

FDA'S EXERCISE OF ITS NEW TOBACCO PRODUCT AUTHORITY

The limited February 2007 to March 2011 window for provisional products caused tobacco product manufacturers to introduce many new products, or to make changes to existing products, before the March 2011 deadline. So long as the manufacturer submitted the required report, those products can continue to be sold. There are apparently thousands of products that fall in this category. FDA has indicated that it is not currently evaluating any of those products, instead reserving its resources in this area for evaluating products commercially marketed after March 2011 that require FDA pre-approval.

Manufacturers that have sought to introduce new products since March 2011,

Further complicating matters is that FDA has taken a broad view of what constitutes a new tobacco product. If, for example, a manufacturer wanted to market "Brand A" cigarette as "Brand B," without changing the cigarette in any way other than the name, FDA takes the position that this is a new tobacco product requiring FDA approval. FDA also takes the position that even minor changes to a product require FDA approval. If, for example, a cigarette manufacturer had its filter supplier go out of business, necessitating a supplier change, FDA takes the position that any change to the filter, no matter how minute, requires FDA approval. This situation presents obvious challenges in the context of a supplier potentially seeking to extract super-competitive prices, knowing the manufacturer cannot readily change. FDA also must pre-approve new manufacturers seeking to sell new products, as well as existing manufacturers seeking to introduce different and potentially innovative products.

The ostensible purpose of the new tobacco product requirements is to ensure that new products are not more harmful than products sold before February 2007, which in itself is a seemingly arbitrary date. In any event, it is difficult to understand how a months or years-long review process is needed to discern that the same product marketed under a different name is more harmful. It is also difficult to discern how minute changes to, for example, a tobacco blend or paper ingredients could significantly alter the risk profile of an admittedly harmful product.

PUBLIC SCRUTINY OF FDA'S NEW TOBACCO PRODUCT AUTHORITY

More recently, FDA has come under fire for its failure to take action on these applications. Articles from the Associated Press and The Atlantic have highlighted FDA's failure to act on these applications, the end result of which has been to freeze the cigarette market as of March 2011. New cigarette manufacturers effectively have been barred from selling their products. Existing manufacturers effectively have been barred from introducing new products, or even making changes to existing products.

Lorillard Tobacco highlighted these concerns in a public petition urging FDA to take action on the new tobacco products. Lorillard correctly pointed out that the Tobacco Control Act's requirement to submit substantial equivalence reports 90 days before market introduction demonstrates Congress' intent that FDA promptly review those reports. Lorillard also noted the Tobacco Control Act's requirement that FDA act, within 180 days, on more detailed reports regarding a product's health risks suggests that FDA's review of less significant changes should be more streamlined. It stands to reason that FDA's review of relatively insignificant product changes should be quicker than FDA's more rigorous

Hestia Tobacco's Long, Bumpy Road to Market

David Sley, chief operating officer at Hestia Tobacco (www.hestiatobacco.com), thought he was well on the way to bringing his startup organic craft cigarette brand to market. Sley, a 28-year-old financial worker in Chicago, set out in 2010 to create the purest cigarette possible, using only flue-cured all-natural tobacco leaf, additive-free paper, and a natural non-toxic filter. "We savor the tastes and aromas of well-aged tobacco," he said in a *Tobacco International* interview. Backed by investors, Sley had no problem sourcing stem- and seed-free organic Virginia tobacco, non-toxic filters, and even a natural paper with algae flame retardants, rather conventional ones containing vinyl acetate compounds. But from day one, the FDA was an obstacle, taking a year alone to approve the brand name (Hestia is a Greek mythological figure who was sister to Zeus and goddess of the communal fire), failing to approve the alternative fire-safe paper, never answering whether cedar aging is a "characterizing flavor," and requiring a mountain of additional—and largely impossible to complete—documentation to support the brand's substantial equivalence report. Sley, seeing no light at the end of the ever-changing tunnel, now and plans to launch Hestia as a filtered little cigar which, at least for now, escapes the FDA's arbitrary and fickle jurisdiction. —*Editor*

review of more substantial changes, yet apparently none of the substantial equivalence filings have been approved within the 180-day window. Lorillard urged FDA to take action on the new products within 90 days, and if FDA fails to do so, Lorillard urged FDA to deem those products as "provisional" products that are not subject to pre-approval.

Unfortunately, FDA has not yet responded to these more urgent calls for action to approve new products.

HOW WILL FDA'S NEW TOBACCO PRODUCT AUTHORITY APPLY TO OTHER TOBACCO PRODUCTS?

As noted above, FDA's initial authority under the Tobacco Control Act was limited to cigarettes, roll-your-own tobacco and smokeless tobacco. However, Congress also gave FDA the authority, through the issuance of regulations, to assert the same authority over other tobacco products, including cigars, e-cigarettes and pipe tobacco. FDA has indicated that it intends to issue the draft regulations by April 2013, although FDA's previous self-imposed deadlines have slipped.

How will FDA's new tobacco product authority apply to other tobacco products? The answer is difficult to discern, as FDA has been notoriously tight-lipped on the content of the proposed regulations. Presumably FDA will not apply the existing requirements to these other tobacco products, since any product introduced or changed since 2007 could not be sold without FDA approval unless the product was sold before March 2011, and the manufacturer submitted the required substantial equivalence reports before March 2011. Presumably, manufacturers did not submit those reports in March 2011 because they were not subject to FDA authority at that time. The industry remains hopeful that FDA will implement a common sense approach that does not disrupt sales of products that are currently on the market.

WHAT WILL FDA DO NEXT?

In response to public criticism, FDA has promised to expedite its review of new products. And while FDA has finally begun to correspond with manufacturers of new products, approximately 500 of these products still remain in the pipeline. Nor has FDA indicated that it will expedite its review of seemingly straightforward applications involving a simple name change or minor ingredient change. Instead, FDA has apparently adopted a "first in, first out" approach that likely allows simpler approvals to languish behind more complicated applications. And, if FDA asserts new product authority over cigars, pipe tobacco and electronic cigarettes, the potential for a bureaucratic logjam increases exponentially.

In the meantime, the industry continues to press FDA to take action. Ultimately, the issue could be decided in court. S

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