SMOKESHOP

THE INDUSTRY AUTHORITY ON TOBACCO RETAILING

Official Publication of the International Premium Cigar & Pipe Retailers Association (IPCPR) | June 2013

A SOUTHERN GENTLEMAN'S ENCLAVE

PJ'S PLUS CIGARS

Oxford, Mississippi

> Why the FDA Might *Not* Want to Regulate Cigars > NATO Show 2013 Wrapup
> Pete Johnson on Tatuaje Cigar's 10th Anniversary

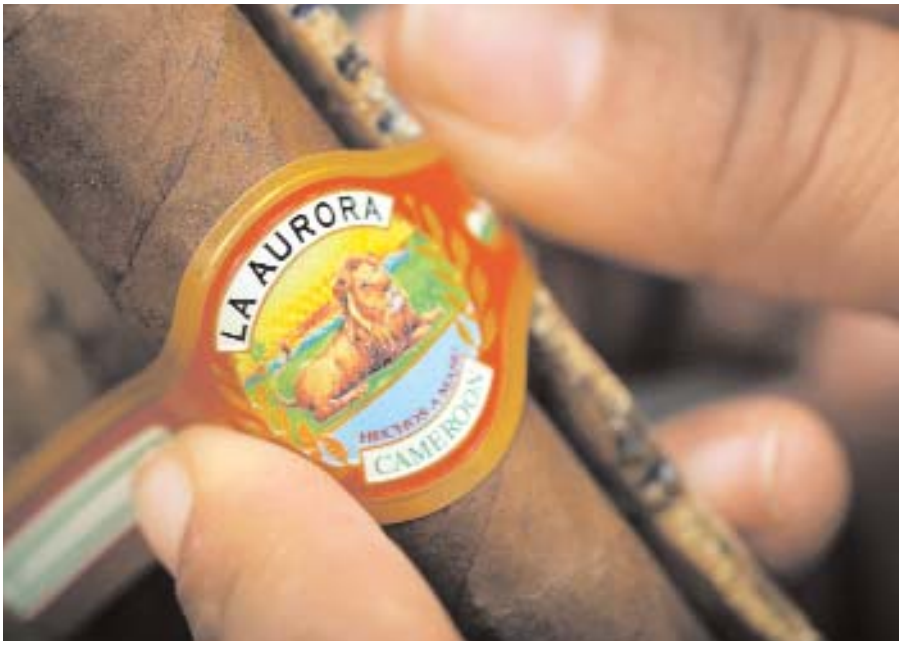


Photo courtesy of ProCigar

Regulating Cigars

The FDA has "deeming regulations" authority, but should the premium cigar industry be regulated under the Tobacco Control Act?

>BY BRYAN M. HAYNES AND ANNE HAMPTON ANDREWS

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"), which gave the Food and Drug Administration initial authority to regulate only cigarettes, roll-your-own tobacco, and smokeless tobacco. A key purpose of the Tobacco Control Act is to ensure that the FDA "has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco," while at the same time continuing to permit the lawful sale of tobacco products to adults. Consistent with that purpose, the Tobacco Control Act prohibits the FDA from banning particular tobacco products.

FDA AUTHORITY TO REGULATE ADDITIONAL TOBACCO PRODUCTS

While the FDA's initial authority under the Tobacco Control Act was limited to specific tobacco categories, the Tobacco Control Act also permits the FDA to issue regulations asserting the same authority over additional tobacco products, including cigars, e-cigarettes, and pipe tobacco.

On December 21, 2012, the White House released its Unified Agenda and Regulatory Plan. The Regulatory Plan serves as a broad outline of the federal agencies' priorities and plans for new regulations for the upcoming year, which included additional regulation of tobacco products. The Regulatory Plan indicated that the FDA intended to issue a proposed rule by April 2013, subjecting additional tobacco products, including cigars, to the FDA's authority. At press time, the FDA had not yet released its proposed rule; this is not the first time it has failed to meet self-imposed deadlines.

THE RULEMAKING PROCESS

A multi-step process governs how a federal agency adopts a final rule, and the FDA must follow this process to regulate cigars and other tobacco products. First, an agency assesses whether a rule might be appropriate to further its priorities and plans. Second, a determination is made whether a rule is needed. FDA has already completed step two of this process. The Regulatory Plan indicates that FDA intends to issue such regulations.

Third, the agency prepares the proposed rule. Fourth, once the proposed rule is prepared, it is submitted to the Office of Management and Budget for review. Fifth, the proposed rule is published in the Federal Register. The sixth step is a public comment period varying from 30 to 180 days depending on the complexity of the rule. At the conclusion of this public comment period, step seven involves preparation of the final rule.

THE PROBLEMS WITH REGULATING CIGARS

Possible impacts of FDA regulation of cigars include, but are not limited to, advertising and marketing restrictions, remote sales restrictions, good manufacturing practice requirements, and user fees. Although there are a whole host of problems with applying the Tobacco Control Act to cigars, there are two primary reasons why doing so will significantly impact the cigar industry. First, cigars are inherently different from cigarettes. Second, a literal application of the FDA's new tobacco product authority to cigars could prohibit the sale of newer or altered products, which would be tantamount to an impermissible ban on premium cigars.

The FDA previously recognized that cigars are different from cigarettes and other tobacco products. In 1996, the FDA issued a rule asserting authority to regulate cigarettes and smokeless tobacco. The FDA did not attempt to regulate cigars. The preamble to the 1996 proposed rule stated that, "[T]he proposed rule would not apply to pipe tobacco or to cigars." The preamble also stated that the "FDA has focused its

investigation of its authority over tobacco products on cigarettes and smokeless tobacco products, and not on pipe tobacco or cigars, because young people predominantly use cigarettes and smokeless tobacco products." In rejecting comments that urged the FDA to regulate cigars, the FDA stated, "there is insufficient evidence of cigar or pipe tobacco use by children and adolescents to support the inclusion of cigar[s]… within the scope of the final rule."

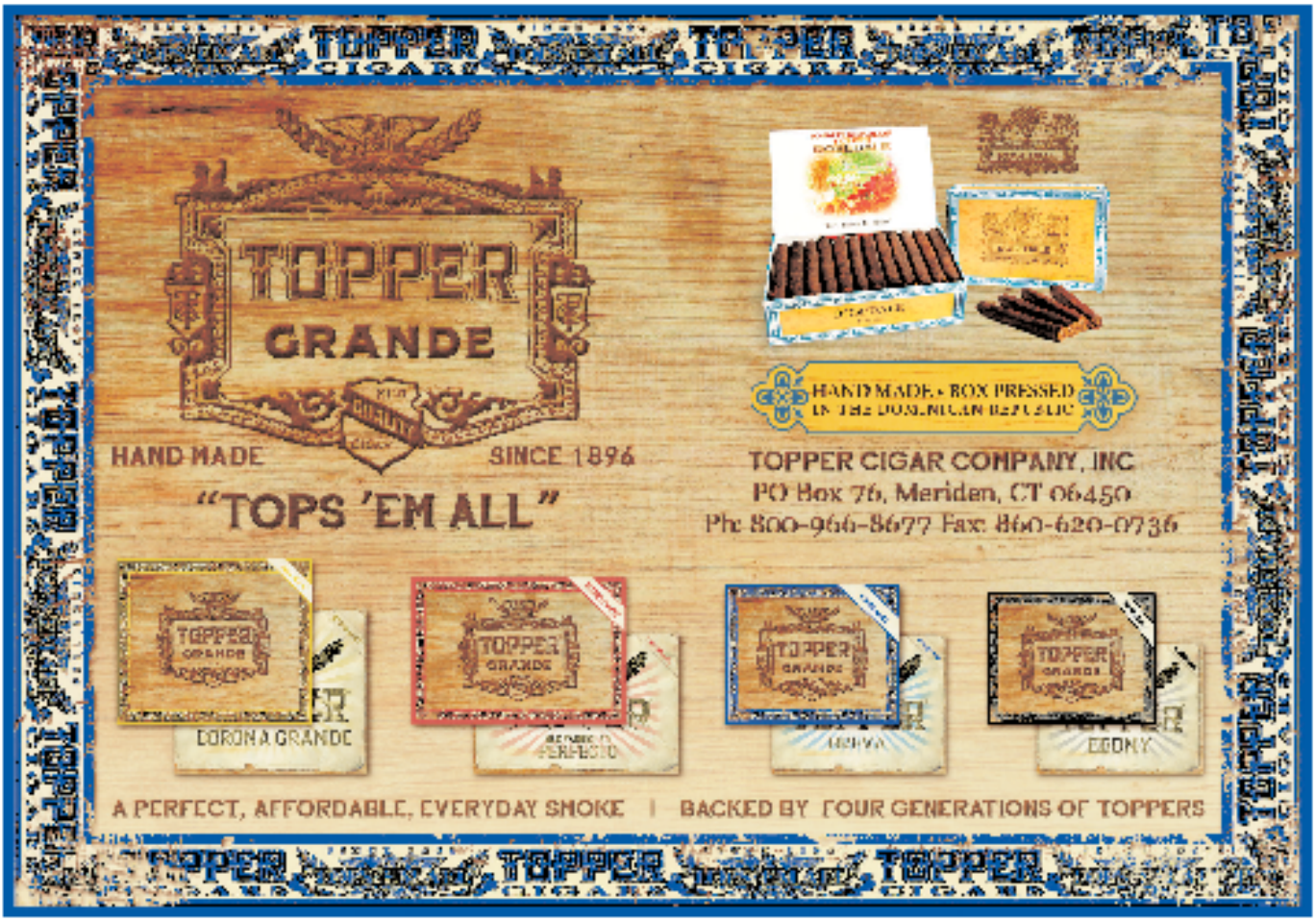
Nothing has changed since 1996. There is still no evidence that minors use cigars in significant quantities. Indeed, as recently as July 2012, the House Appropriations Committee reminded the FDA that, "Premium cigars have unique characteristics and cost-prohibitive price points and are not marketed to kids" and that "[a]ny effort to regulate cigars should take these items into consideration."

In response to the FDA's plan to regulate cigars, the U.S. House of Representatives introduced House Bill 792 on February 15, 2013. House Bill 792 proposes to amend the Food, Drug, and Cosmetic Act to clarify the FDA's jurisdiction over certain tobacco products, and to protect jobs and small businesses involved in the sale, manufacturing, and distribution of traditional and premium cigars. On April 18, 2013, the U.S. Senate introduced Senate Bill 772 as a companion bill to House Bill 792. The purpose of the bills is to retroactively strip the FDA of its authority to regulate premium cigars. Generally, the bills define "premium cigars" as any roll of tobacco weighing at least six pounds per 1,000 count that is wrapped wholly in leaf tobacco; does not contain a filter, tip, or non-tobacco mouthpiece; is made by hand; and is not a cigarette or little cigar by definition.

APPLYING FDA'S NEW PRODUCT REQUIREMENTS TO CIGARS

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 not been changed in any way since February 15, 2007. Generally, new tobacco products cannot be commercially marketed without an order from the FDA.

There was a limited window for new tobacco products commercially marketed in the United States before March 22, 2011, so long as the manufacturer submitted a report prior to that date describing how the product is "substantially equivalent" to a product commercially marketed prior to February 15, 2007. Tobacco products that fall within this limited time frame are known as "provisional products." This limited window prompted cigarette, roll-your-own tobacco, and smokeless tobacco product manufacturers to introduce many new products, or to make changes to existing products, prior to the March 2011 deadline. Those products can continue



to be sold so long as the manufacturer submitted the required reports. The FDA is not currently evaluating those products, but reserving its resources for evaluating tobacco products commercially marketed after March 2011, which require FDA pre-approval.

Manufacturers that have sought to introduce new products since March 2011, or to modify existing products, are in a much more difficult position. Again, those products require pre-approval before they can be sold. Apparently the FDA has not acted on any of those applications, some of which have been pending for more than two years, and 90 percent of which have been pending for more than one year. the FDA has come under scrutiny for its failure to take action on these applications.

How will the FDA's new tobacco product authority apply to cigars? If applied literally, any cigar introduced or changed since February 2007 cannot be sold without FDA approval unless the cigar was sold prior to March 2011 and the manufacturer submitted the required substantial equivalence report prior to March 2011. It is not likely that cigar manufacturers submitted those reports by March 2011 because cigars were not subject to the FDA's authority at that time. Under this application of the new tobacco product requirements, all cigars commercially marketed after February 2007 must be removed from the market until the FDA has approved the product. Based on current practice, FDA approval will likely take over a year. This would be tantamount to a ban on cigars, which is impermissible under the Tobacco Control Act.

Application of the new tobacco product requirements to cigars will present financial challenges for cigar manufacturers not faced by cigarette manufacturers. While cigarettes are homogenous and consistent products, hand-made cigars are "small batch" products. There are often minor variations intended to alter the taste or aroma of the new product. Such variations would trigger a time-consuming and expensive review process, without any discernible impact on public health. Even brands that have been on the market before February 2007 may be considered new products because of various changes to the product composition.

Although FDA may have authority to regulate premium cigars, that does not mean it should. As Congress has already noted, premium cigars have unique characteristics that suggest a different regulatory standard than for other tobacco products. And if FDA fails to take those unique characteristics into account, Congress appears poised to take corrective action.

Troutman Sanders Tobacco Team, Troutman Sanders LLP, *1001 Haxall Point, Richmond, Va. 23219, Tel: (804) 697-2206, Fax: (804) 697-1339, Web: www.troutmansanders.com, Email: bryan.haynes@troutmansanders.com.*