# SMOKESHOP

THE INDUSTRY AUTHORITY ON TOBACCO RETAILING

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## TESA CIGARS

**Self-Taught Blender Chris Kelly Produces Cigars at his Family's Nicaraguan Factory for His Chicago Cigar Shop & Lounge**

***Plus:***

> **WHAT THEY SAID:**
*Industry Comments on FDA Deeming Regulations*

> **M&R HOLDINGS:**
*U.S.A.'s Largest Private Label Tobacco Producer Keeps at the Forefront of Trends*

> **DREW DIPLOMATS:**
*Innovative Cigar Maker Drew Estate Adds a New Twist to Incentive Program*


# Premium Cigars Face Regulation Strangulation under FDA

*The potential impact of FDA pre-market review requirements on the premium cigar industry can be underestimated: small makers and small batch releases would be in jeopardy unless separate rules are implemented for cigars.* **> BY NANCYELLEN KEANE, ESQUIRE**

In the five years since the Tobacco Control Act was enacted in June 2009, giving the United States Food and Drug Administration (FDA) regulatory authority over certain tobacco products, very few new tobacco products have been approved under any of the three pathways to approval: Substantial Equivalence, Exemption, or Pre-market Tobacco Application.

The results of passing this law have been to limit product innovation, prevent changes that could benefit public health, and to place a significant barrier to entry into the portions of the industry related to cigarettes, smokeless, roll-your-own and cigarette tobacco. Despite few approvals and relatively few actions taken by FDA on enforcement matters for the products it currently regulates, and a lengthy back-log of existing pre-market review applications in the existing tobacco categories, the agency is pressing forward with its request to add more products to its purview via deeming regulations.

## WHAT ARE DEEMING REGULATIONS?

FDA seeks to expand the definition of tobacco products to add such products as cigars, pipe tobacco, and e-cigarettes to its portfolio. The agency recently received over 50,000 public comments about this proposed regulation and is reviewing those at this time. Members of the public and stakeholders in each of these product areas have weighed in on how expanding the regulation to cover their product will affect their interests. It is expected that a decision will come in 2015 regarding whether and to what extent the current law will be deemed to apply to additional products. It is clear that FDA is seeking a one-size-fits-all approach, where most if not all existing regulations would apply to these additional types of tobacco products.

## OVERVIEW OF CURRENT PRE-MARKET REVIEW REQUIREMENTS

Current pre-market review requirements apply to manufacturers of cigarettes, smokeless, roll-your-own, and cigarette tobacco. The purpose behind pre-market review of new tobacco products is to confirm that new products are not more dangerous than grandfathered or provisional products. "Grandfathered" products may be introduced into U.S. commerce without prior approval from FDA, as these were in U.S. commerce as of February 15, 2007. Any of these products changed or introduced after February 15, 2007 is considered a new product. Those introduced between February 15, 2007 and March 22, 2011 are given an intermediate "provisional" status by FDA, allowing them to remain in commerce until approved or denied by FDA. After March 22, 2011, any change to an existing product results in a new product requiring pre-market review and approval by FDA before introducing the product into commerce. New tobacco products that are sold without the required FDA order are deemed to be adulterated and cannot be legally sold. Thus far, pre-approval by FDA is not a simple concept and has not proven to be quick or inexpensive.

## RELEVANT CONSIDERATIONS FOR THE CIGAR INDUSTRY

For planning purposes, cigar manufacturers should prepare as if the current regulations will apply, although it is not yet clear whether they will apply without changes. There is a proposal pending to exempt a defined category of premium cigars from regulation, and if accepted, then these products would not be regulated. If the very same regulations were to apply, then cigar makers should expect most of the same requirements as currently exist for pre-market review of new products. Pre-market review will pose unique burdens for cigar manufacturers.

> Bringing to market small batch releases, such as micro blends from Foundry Tobacco Co. *(above)* or the increasingly popular seasonal blends from many makers, could be nearly impossible for all but the largest manufacturers under FDA pre-market review requirements currently in place for cigarettes. Facing as many as 5,000 man-hours of costly testing, premium makers might have to rethink the feasibility of "one-out" releases if a premium exception isn't granted.

■ ***Pre-Market Review is Disproportionately Burdensome for Cigar Manufacturers.*** These burdens include that cigars are artisanal and not homogeneous, and thus there are numerous products with slight variances, resulting in disproportionate and costly requirements on cigar manufacturers. Since many cigars will have slight variations, then the FDA interpretation that virtually every change results in a new product for which FDA prior approval is necessary, will greatly damage the industry. If the FDA holds to this interpretation, it is still unclear how current FDA scientific review requirements can be applied to cigars. Many of the qualitative and quantitative questions posed will result in inconsistent answers. Without appropriate changes to the regulations, or interpretation of them, the result could greatly harm the category.

FDA takes a broad view of what constitutes a new product requiring pre-market review by FDA. Therefore, from the effective date of a new regulation, companies may immediately find that some products will automatically become new products and that changes made to products after a stated date will cause them to become new products. Any change, even taking the exact product and marketing it with a new name, or the exact product in a spruced-up package, renders the product a new tobacco product, subjecting it to pre-market approval by FDA.

Extending a brand to take the exact product sold in a soft pack and adding a hard pack version of the same name is considered a new product which requires pre-market approval. Pre-market approval via one of the three available pathways (substantial equivalence of a new product compared to a grandfathered product, exemption from substantial equivalence for certain narrow tobacco additive changes, new product application) is labor-intensive, time consuming, and costly, and only recently has any product been approved under any of these pathways, with companies waiting over a year after filing an application with FDA just to receive an acknowledgement of receipt.

Even after the initial regulation goes into effect with immediate changes in status to certain products currently on the market, the pre-market review requirement will continue into the future to prevent cigar manufacturers from taking initiative to improve products by changing to better designs, extending product lines, or buying better raw materials. Every time any design change or raw material change is suggested, the FDA approval process is required and is lengthy and costly, and is expected to become a disincentive to pursuing product improvements.

If the grandfather date remains February 15, 2007, numerous cigar products which companies spent time and money to develop will be converted overnight to provisional or new products. For example, companies that did not exist in February 15, 2007 or which launched a product after that date will be placed in a position of having to stop manufacturing these, or else acquire very expensive predicate product data to enable a comparison of the company new/changed product to a grandfathered product for pre-market review purposes.

The current proposal provides for a two year window for the intermediate "provisional" status, so a cigar manufacturer would have two years from the effective date of the deeming regulation to get a product to market and submit an application for pre-market approval in order to continue introducing the product until FDA rules on it. Products launched after the two year deadline would be considered new products which would require prior FDA approval as a condition to introduction to market.

Cigar manufacturers should be thinking about ways of softening the potential impact of the deeming regulations before they are faced with the realities of implementation. It is unlikely that FDA will freely allow extensions of time to respond to their inquiries or comply with enforcement demands as it once did at the outset of its tenure as tobacco regulator. There is no time like the present for considering the following:

■ ***Nail Down Supplier Arrangements.*** Confirm that you have written supply agreements with reputable suppliers that determine the identity and level of the raw material to be purchased, including ingredients, design and specifications. Your agreements should prohibit any changes in the identity, ingredients or method of manufacture by your supplier. Require that your supplier cooperate in a timely manner in disclosure of information about its product. Problems have been experienced with suppliers that are not willing to provide the information needed by the manufacturer to satisfy FDA requests. FDA will not call suppliers to obtain this information. This is among the most time consuming parts of the process and should be started now.

FDA review is not a quick fix for a commercial problem. Commercial problems should be anticipated if possible to avoid a situation where the company is seeking any expedited review or assistance from FDA. This will not be forthcoming. FDA will not review applications in an emergency, for example when there is interruption in supply, or a raw material supplier unilaterally decides to close or move production and thus make slight changes in the raw material sold to a manufacturer. FDA will not assist in these situations and advises that it reviews all applications for new products in order received, first in—first out.

FDA offers a program called Tobacco

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Product Master File ("TPMF") which is described as a means for suppliers, often reluctant to disclose ingredients, to provide the information FDA requires directly to FDA. Experience has shown, however, that this option is of more interest to FDA than it is to suppliers and manufacturers. Even if a supplier pledges to participate in this program, often they do not. This is a last choice for manufacturers because they will lose control of the process pertaining to their own product application. A supplier may promise the manufacturer it will participate, but may never submit the information to FDA. The manufacturer may not know if and when the information is submitted to FDA. Finally, if the application is denied by FDA, the manufacturer will never be able to see the information that the supplier submitted directly to FDA under the TPMF, and thus, will not be able to address or correct the issue which may have caused or contributed to the denial.

■ ***Confirm Ownership of Valuable Intellectual Property***—Confirm in written agreements that your company owns all necessary product intellectual property, even if manufactured by a contract manufacturer. This is extremely important in situations where your brand is being manufactured in another country. Experience has shown that it is difficult to get rights to this material and information after the fact. Your agreement should address trademark, copyright, trade secrets, design, recipe, specifications, and documentation evidencing status as grandfathered or provisional. If you do not own and physically hold in your possession the necessary rights and documentation, then you can be out of luck, unable to provide the information and documents required by FDA. FDA will not contact others to get them.


> The E.P. Carrillo Inch Short Run 2014 series was a blend variation of the company's regular production E.P. Carrillo Inch, limited to 1,500 boxes of each of three sizes. FDA could consider releases like this brand new products, subject to extensive pre-market testing to prove it's not more dangerous than existing grandfathered products.

■ ***Confirm Status of Products—Grandfathered, Provisional or New?*** Are your products grandfathered? Do you have documentation of sales in the United States of each style of product as of February 15, 2007? If your products were not in market as of February 15, 2007, or you did not start in business until after that date, or you introduced a new product after February 15, 2007, then you should be thinking now about where to find a predicate product that is similar to yours that will enable you to compare your product either as a provisional or new product via the Substantial Equivalence application process. Without a predicate product you may have to cease making a current product unless and until FDA has approved the product. This can take years. If you were in business with products in market as of February 5, 2007, were changes made to your product after February 15, 2007? What were the changes and the dates of changes? Each change constitutes a new product. There may be a provisional status window, although it is not clear when that will be. Nevertheless, you should start preparations in making these inquiries now. This process can take an extended period, and should be in process well before the regulations are in force.

■ ***Make Business Case for Product List, Changes to Products.*** Review your product list and give thought to the appropriate number of SKUs for your business model. Each product carries a real cost, which will increase as time progresses. A business case should be made before making product changes going forward. Each change will require a couple of years to get approved and the costs will not be insignificant. The foregoing regarding carrying costs should be weighed against the reality that all grandfathered and provisional products are valuable. Once the deadline dates are established, there is a fixed universe of these products. Their value will increase if they are compliant products. Their value will increase, as will their costs for carrying them and keeping them compliant. S

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