

SUMMARY OF INFORMATION PROVIDED TO OMB-OIRA BY SMALL BUSINESS
CIGAR COALITION RE: FDA DEEMING RULE (RIN 0910-AG38)

November 21, 2013

A. Authority of Tobacco Control Act

- Extended to Other Tobacco Products. Under the authority of the Family Smoking Prevention and Tobacco Control Act (TCA), the statute (as administered by FDA) “shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be the subject of this chapter.” §901(b) FDCA.
- APA Applies. Each rulemaking under the TCA shall be in accordance with chapter 5 of Title 5 of the USC (Administrative Procedure Act). §901(d) FDCA.
- Consult with Other Federal Agencies. Prior to promulgating rules under the Act, FDA shall endeavor to consult with other Federal agencies as appropriate (e.g., OMB, FTC, Treasury-TTB, USDA, etc.). §901(g) FDCA.
- Appropriate to Protect Public Health. Any restrictions in the deeming rule on the sale and distribution of cigars requires a determination by FDA that “such regulation would be appropriate for the protection of public health.” §906(d)(1).

B. Authority of EO-12866 and EO 13563

- Improve Economic Performance. The regulatory system proposed must protect and improve the public’s health, safety, environmental and well-being and improve the performance of the economy (creating jobs) without imposing unacceptable or unreasonable costs on society.
- Assess All Costs & Benefits. Agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating (Sec. 1).
- Qualitative and Quantitative Measures. Provide qualitative and quantitative measures of costs and benefits.
- Maximize Net Benefits. Select the approach that maximizes net benefits (including potential economic advantages).
- Identify Problem. Identify the problem it intends to address (and the significance of the problem).
- Least Burden on Businesses. The regulation should be tailored to impose the least burden on businesses of differing sizes taking into account the costs of cumulative regulations.

C. Characteristics of Cigars

Cigars are very different than cigarettes or other tobacco products FDA currently regulates.

Cigars	Cigarettes	Impact on Proposed “Deeming” Rule
Many more and smaller regulated entities—(4%-7% size of cigarette industry); more foreign entities; more cigarettes sold in 2-weeks than cigars in entire year.	Fewer and larger companies; primarily located in U.S.	Less ability to comply with TCA requirements; larger potential disruption to existing market.
Many thousands of different sizes, shapes and compositions defined by length and ring gauge (filtered, tipped, cigarillos, blunts, leaf wrapped, reconstituted wrappers, long, short, large like panatelas, coronas, Churchill’s, etc.)	One or two sizes and shapes.	Impacts registration and product listing, ingredient listing, reporting of smoke constituents, testing criteria, GMP requirements, establishment inspections, volume and content of SE Reports, etc.
Manufacturing either machine-made, hand-rolled, or both, with hand-rolling generally outside U.S. in foreign jurisdictions (2.8 billion cigars imported to US in 2010); widely variable methods of construction; imported tobacco commonly used as filler (65 million lbs. of cigar leaf tobacco imported to US in 2010).	Machine-made primarily in U.S.	Different registration and product listing requirements, enforcement, constituent testing, ingredient listing variances, GMP requirements, labeling.
Filtered, tipped, rounded or cut ends.	Mostly filtered with a few variations.	Volume and content of SE Reports, testing criteria, GMP requirements.

Cigars	Cigarettes	Impact on Proposed "Deeming" Rule
Wrappers brown leaf tobacco or reconstituted tobacco (66% leaf tobacco preserving its tobacco character (taste, aroma, identifiable chemical components) as required by TTB.	Wrapper white paper; most states now require particular low ignition propensity paper designs.	Larger no. and variance in product listings, ingredient listings, testing methodologies, SE Report filings and GMP requirements.
Filler composed largely of harsher air-cured low-sugar burley tobacco blends.	Filler composed of sweeter higher sugar flue-cured blends of Oriental tobaccos.	Product standards may need to be considered.
Historically flavored including hundreds of propriety blend flavorings and characterizing flavorings (~80% of all cigars); consumer-driven to create distinctive aromas and tastes promoting brand loyalty.	Few, if any, characterizing flavors; now illegal by statute, except menthol (under review).	Huge volume of SE Reports, product and ingredient listing difficulties (proprietary flavoring blends from specialty companies); no statutory requirement prohibiting flavorings; supportive administrative record required if limiting flavorings to avoid arbitrary, capricious action, or abuse of FDA discretion.
Smoke generally not-inhaled.	Smoke generally inhaled.	Different testing methodologies and HPHC constituent levels.
Occasional use and generally smoked in lower numbers; less addictive.	More frequent use and smoked by the pack (containing 20 sticks).	Differing testing methodologies and public health considerations (e.g., restrictive regulation could increase cost; narrow consumer choice and increase cigarette use).

Cigars	Cigarettes	Impact on Proposed "Deeming" Rule
Marketing and promotion practices include <i>de minimis</i> print advertising, non-face-to-face sales (e.g., Internet, mail-order); sampling in tobacco shops; aficionado clubs; wider variety of retail locations; etc.	Face-to-face retail sales with large advertising budgets.	Inappropriate application of 21 CFR §1140 (marketing and advertising restrictions) applied by statute to cigarettes, smokeless and RYO.
Packaging variety including, hard pack, soft packs, singles, doubles, 3-5 packs, resealing foil packs, cellophane, humidors, wooden boxes, etc.	Same 20-pack cellophane wrapped, foil-lined hard or soft paper boxes.	Huge volume of SE Reports; bottleneck for technological packaging changes to preserve moisture and extend product life.
Most proprietary names also used by non-tobacco products (e.g., Durango, Riptide, Aura, etc.)	Smaller number of established product names.	Inconsistent with TCA prohibition on use of trade names.

D. Public Health Rationale

If the stated purpose of regulating cigars currently under the TCA is to curtail a perceived increase in use of flavored filtered cigarillos by under-age smokers, please consider the following:

- Focus on Re-review of CDC Data. Proponents of increased FDA regulation have touted recent meta-analyses by three employees of CDC (expressly disclaimed in the article as representing the official position of CDC), and a CDC reanalysis focusing on use of flavored little cigars.
- Inconsistent Government Data. While some recent CDC analysis of 2011 data from the National Youth Tobacco Survey reportedly found a slight increase in self-reported cigar use (at least once in last 30-days) among non-Hispanic blacks (7.1% in 2009 and 11.7% in 2011), the larger and more recent annual SAMHSA-administered National Survey on Drug Use and Health found that 2012 cigar use among persons aged 12 to 17 (2.6%) continued to decline significantly from peaks in 2004 (4.8%).
- Different Patterns of Use. Low levels of underage cigar use is logical because of the different characteristics/patterns of cigar use; harsher air-cured burley tobaccos not

intended to be inhaled; less advertising and status name brand recognition; occasional use in fewer numbers (e.g., see NCI Monograph 9 (NIH Publication No 98-4302 (1998))).

- TTB Data Shows Declining Cigar Sales. Department of Treasury- Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Reports for 2012 and 2013 report significant decreases in the sale (removal) of both large and small cigars in the U.S.; 4.7 billion units of large cigars (2013 year-to-date) v. 6.4 billion (2012 year-to-date); and 612 million small cigars (2013) v. 730 billion (2012).
- Companies Report Declining U.S. Cigar Sales. These figures coincide with SBCC Member reports of decreased sales in both large and small cigar categories.
- More Study Needed. FDA issued a RFP and selected an economic consulting firm to compile and study this type of data and consumer use and perceptions of flavored cigars. If evidence is presented, for example, that consumers are confused concerning the identity of filtered cigars and cigarettes, FDA has the power to regulate these cigars under the definition of cigarettes.
- No Public Health Emergency. A public health emergency or health crisis does not exist to justify an immediate need for FDA cigar regulation.

E. Cigars already regulated; any FDA regulation should be consistent with existing rules

- Increased State Enforcement. Systems are already in place to protect youth and inform consumers--- Increased State enforcement exists at the retailer level of age restrictions and use of valid photo identification paid for, in part, from TCA user fee resources in grants to states. All state cigarette requirements also apply to cigar sales including behind the counter display requirements and indoor smoking bans. Internet and mail-order sites contain controls and age verification software using sophisticated on-line programs.
- FDA Recommended Not Regulating Cigars. FDA made a finding in 1995, when initially asserting jurisdiction over tobacco, stating "FDA has focused its investigation of its authority over tobacco products on cigarettes and smokeless tobacco products, and not on pipe tobacco and cigars, because young people predominately use cigarettes and smokeless tobacco products." (Prop. Rule, 60 Fed. Reg. 41322 (Aug. 11, 1995))
- Consent Decree with FTC. In 2000, cigar companies representing 95% of the cigar market voluntarily entered into a Consent Decree with the Federal Trade Commission (FTC) dictating a uniform federally-mandated system of health warnings in cigar packages and advertisements nationwide (see <http://www.ftc.gov/opa/2000/06/cigars.shtm>). Five rotating Surgeon General's warnings appear in black text, with a white background, on all cigar packages, advertisements and utilitarian items.
- TTB Enforces Tax Ruling. ATF Ruling 73-22 (1973) enforced by TTB differentiates clearly a cigar from a cigarette (for excise tax purposes) by wrapper, filler and conspicuous labeling. FDA is, likewise, entitled to regulate a cigar as a cigarette under the TCA if based on

appearance, type of tobacco in the filler, packaging and labeling, the product is likely to be offered to, or purchased by, consumers as a cigarette or RYO. §900(3) FDCA.

F. FDA Regulation Under TCA Has been Very Tough; No Small Business Protection

- SE Standards Increasingly Stringent. Newly available public records of FDA SE Orders demonstrate that out of over 3,800 reports in cue, only a few substantive orders have been granted finding products marketed since 2007 to be substantially equivalent with predicates (9 orders with only 2 relevant to cigars), 13 products deemed not substantially equivalent and 162 report withdrawals. The two SE determinations relevant to cigars involved granting Lorillard the right to market cigarettes without menthol and using fire safe paper. These reports took three years to resolve, involved three rounds of requests for volumes of additional testing data, and 7 referrals to interdisciplinary review branches within the CTP Office of Science (e.g., toxicology, engineering, environmental, regulatory, marketing, etc.), *see* <http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm339928.htm>; and recent GAO Report (*see* <http://www.gao.gov/products/GAO-13-723>).
- Malfunctions in eSubmitter System. Registration and filing requests are directed to an electronic submission system (eSubmitter-Electronic Gateway). The system is confusing, has malfunctioned and is being supplemented for internal FDA use by its FURLS System which may replace eSubmitter in its entirety. Hundreds of hours per company have been lost entering and reentering data into this system which continues to malfunction.
- No Small Business Protection. FDA-CTP has honored few if any of the protections built into the TCA to protect small businesses. The mandated Office for Small and Disadvantaged Businesses has never been established or staffed. Company compliance questions directed to a designated CTP email site largely do unanswered. The few meetings granted offer no guidance or answers. GMP inspections continue without GMP guidance or regulations. Companies, including small businesses were required by Guidance to test 20 HPHCs without required testing regulations or transition relief required by statute to prevent inaccessibility and price-gauging by testing labs.
- No Additional Agency User-Fee Resources. FDA gets no additional resources (user fees) if it expands jurisdiction to include cigars. Existing fee structure is reallocated based on market share and percentage of excise taxes paid. FDA Commissioner Hamburg complained recently in a New York speech to the Bloomberg organization about expanded jurisdiction without expanded resources.

G. Recommendations

- Plan to Meet Existing Obligations. Request a plan from FDA demonstrating that it has the ability to meet its existing statutory/regulatory responsibilities and deadlines under the TCA for cigarettes, smokeless and RYO before it expands this jurisdiction.

- Demonstrate Ability to Regulate Cigars. Ascertain that FDA has the ability to regulate simultaneously cigars and other tobacco products.
- Assist FDA to Prioritize Resources. Consider assisting FDA to prioritize its resources by deeming one class of additional products at a time as covered by the TCA based on an established need for additional regulation; e.g. begin with e-cigarettes where little regulation currently exists and FDA resources can help resolve pending issues and uncertainties.
- Tailor Regulation to Unique Features of Cigars. If cigars are to be deemed “tobacco products” under §901(b), triggering application of the TCA, the deeming regulation should be tailored in the following suggested manner:
 - Reset All Transition and Compliance Dates. All the compliance dates and transition dates in the TCA must be reset and readjusted to provide reasonable timeframes and notice for FDA and industry to provide required information.
 - Prioritize TCA Requirements. In the alternative, the Proposed Rule could state FDA’s intention to not enforce existing compliance and transition dates, but to use its enforcement discretion to prioritize regulatory responsibilities and announce new dates in the future based on the following considerations: (1) the agency’s ability and resources to review and use that information in a timely manner; (2) proven reliability, consistency, clarity to users, and performance of the eSubmitter Electronic Gateway or any other electronic databases; (3) reasonable time periods for companies to respond comparable to the time periods granted to cigarette manufacturers following enactment of the TCA; (4) acknowledgement that small businesses require additional assistance and transition relief similar to the provisions included in the TCA; (4) first identifying companies and products through establishment registration and product listing; (5) then requiring ingredient listing; (6) consideration of any product standards, including review of cigar flavorings, only after TPSAC review and use of a process similar to the process used to evaluate menthol in cigarettes; (7) not to require submission of any HPHC data until regulations are promulgated establishing agreed to product testing methods, (8) promulgation of regulations related to marketing and promotion of cigars that preserve and address existing practices including sampling and mail order and Internet sales; and (9) express acknowledgment that cigars are different than cigarettes and that evaluation of manufacturing, labeling, packaging, constituent testing, substantial equivalence, and other requirements will be determined by subsequent guidance and regulation based on these differences.

H. Legal Authority

To be provided shortly by SBCC legal counsel upon OMB-OIRA request.

