



Talking Points – FDA Deeming Rule

- May 5, 2016, FDA released their final rule deeming premium cigar subject to regulation through the “option 1” framework.
- “Option 1” regulation will require premium cigar manufacturers to list ingredients of products and Harmful and Potentially Harmful Constituents (“HPHC”), which is based upon questionable science, lack of in-depth analysis, and no premium cigar specific studies upon which to base this requirement.
- FDA’s regulation of premium cigars will result in a ban on free samples for adults of legal age.
- “Option 1” regulation will require six rotating health warning labels that must cover 30 percent of the product packaging, which is based upon questionable science, lack of in-depth analysis, and no premium cigar specific studies upon which to base this requirement. This requirement will result in altering the traditional artistic design and production of premium cigar packaging.
- New regulations will threaten up to 35,000 jobs in the United States and over 300,000 in Latin America.
- Premium cigar manufacturers will be required to obtain pre-market authorization for products, resulting in higher prices for consumers and companies alike, which by the analysis of U.S. Small Business Administration and the FDA will result in 50 percent of the market being eliminated, due to these burdensome and unprecedented regulations.
- “Option 1” regulation will result in new user fees, which is in fact a new tax on premium cigars and is a regressive measure impacting community retail tobacconists and consumers alike.

For additional information, please contact CRA directly at 1.800.460.0729 or at info@cigarrights.org