CONGRESSIONAL, INTERNATIONAL, STATE & LOCAL CORRESPONDENCE ADDRESSING PROPOSED REGULATIONS ON PREMIUM CIGARS BY THE U.S. FOOD AND DRUG ADMINISTRATION

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EXECUTIVE SUMMARY

The purpose of this briefing book is to provide a chronology of correspondence that has been generated on the subject of regulating cigars, and specifically, to provide a comprehensive collection of the messages from Congress, State and Local Officials, and third-party organizations that have a vested interest in protecting the unique character of premium handmade cigars.

On April 15, 2011 the premium cigar industry initiated its first ever legislative effort to protect itself from onerous regulations. It was on that day that Congresswoman Kathy Castor (D-FL) and Congressman Bill Posey (R-FL), joined together in a bi-partisan fashion, and introduced legislation to exempt premium handmade cigars from federal regulation.

Throughout the course of the 112th, 113th and 114th sessions of Congress, 283 current and former members of the House of Representatives and 26 current and former members of the Senate have co-sponsored *The Traditional Cigar Manufacturing and Small Business Jobs Preservation Act*.

Of these 283 Members of Congress, twenty-one were the chairs of committees, and it includes numerous physicians and nurses. More importantly, however, of those 283 seventy-three voted in favor of the original *Family Smoking Prevention and Tobacco Control Act*, meaning there was recognition as to premium cigars being in a distinctive class, not warranting such regulatory scrutiny.

These 283 members of the House of Representatives and 26 members of the Senate hail from 43 states. Among them, thirty-five have either individually or in joint letters with their colleagues, written the President's Administration in defense of premium cigars, and they are provided in this report.

These legislators have carried the message to key committees within the Congress. Consistently since 2011, the House Committees on Appropriations, Foreign Affairs, Energy & Commerce, Oversight & Government Reform as well as Small Business, have been briefed on our issue. In addition, the U.S. Senate Committee on Foreign Relations, Appropriations and Health, Education, Labor & Pensions, and Small Business Committee have received briefings and information on why cigars simply don't deserve this type of regulatory treatment, as proposed by the U.S. Food & Drug Administration.

And, premium cigars are not a partisan issue. The support for a premium cigar exemption from FDA rules includes 219 Republicans and 64 Democrats in the House of Representatives and of the supporting co-sponsors in the Senate, fifteen were Republicans and eleven Democrats, which in the current political climate, represents a bi-partisan consensus.

The message as to the harm these regulations would bring to premium cigars is also being heard well beyond the halls of Congress. The Department of Health & Human Services, the Department of Agriculture, the Department of Homeland Security, the Department of State, the Department of Commerce, the U.S. Small Business Administration and the National Security Council have each been briefed, received correspondence, and been informed on the implications of regulation.

There have been 350,000 petitions to Congress and over 40,000 to The White House in support of a premium cigar exemption from regulation. A significant number of the 135,000 public comments received by the FDA between April 25, 2014 and August 25, 2014, were also in support of exemption.

It is also significant to note that within this briefing, the Embassies of Honduras, Nicaragua and the Dominican Republic have made their concerns known, through the attached correspondence to the State Department, Commerce Department, Food & Drug Administration, National Security Council, Department of Agriculture, Small Business Administration, and Department of Homeland Security. These Ambassadors have also sent this correspondence to the membership of the Senate Committee on Foreign Relations and House Foreign Affairs Committee.

The implications of regulation are also local. Hence, correspondence is attached representing the concerns from the Mayors of Tampa, Miami and Las Vegas, coupled with issues raised on local economic impact from non-cigar associated organizations such as chambers of commerce, retail associations, hospitality sector, and agricultural interests, as well.

We believe that this compendium of correspondence depicts the concerns of a broad cross-section of officials, agencies, organizations and indeed, nations, on the issue of regulating premium handmade cigars. It substantiates that there are numerous unanswered questions on this matter, and the need for a deeper understanding as to the implications for regulating this artisan and culturally significant product, in the fashion presented.

Members of Congress That Support a Premium Cigar Exemption --- 112th-114th Congress

Title	Name	Party	State and District
Representative	Don Young	R	AK–At L
Representative	Jo Bonner	R	AL-1
Representative	Bradley Byrne	R	AL–1
Representative	Tim Griffin	R	AR-2
Representative	Mike Ross	D	AR-4
Representative	Eric A Crawford	R	AR–1
Representative	Steve Womack	R	AR–3
Representative	Tom Cotton	R	AR–4
Representative	Benjamin Quayle	R	AZ-3
Representative	Ed Pastor	D	AZ-4
Representative	David Schweikert	R	AZ-5
Representative	Dennis A. Cardoza	D	CA-18
Representative	Jeff Denham	R	CA-19
Representative	Jim Costa	D	CA-20
Representative	Howard P. "Buck" McKeon	R	CA-25
Representative	Tom McClintock	R	CA-4
Representative	Gary G. Miller	R	CA-42
Representative	Joe Baca	D	CA-43
Representative	Ken Calvert	R	CA-44
Representative	Dana Rohrabacher	R	CA-46
Representative	John Campbell	R	CA-48
Representative	Jeff Denham	R	CA–10
Representative	David G Valadao	R	CA–21
Representative	Devin Nunes	R	CA–22
Representative	Stephen Knight	R	CA–25
Representative	Tony Cardenas	D	CA–29
Representative	Edward R Royce	R	CA–39
Representative	Loretta Sanchez	D	CA–46
Representative	Darrell E Issa	R	CA–49
Representative	Duncan D Hunter	R	CA–50
Representative	Paul Cook	R	CA–8
Representative	Cory Gardner	R	CO-4
Representative	Ken Buck	R	CO-4
Representative	Doug Lamborn	R	CO-5
Representative	Mike Coffman	R	CO-6
Representative	Ed Perlmutter	D	CO-7
Representative	Jared Polis	D	CO–2
Representative	Scott R Tipton	R	CO–3
Representative	John B. Larson	D	CT-1
Representative	Joe Courtney	D	CT-2
Representative	Jeff Miller	R	FL-1
Representative	Bill Posey	R	FL-8
Representative	C. W. Bill Young	R	FL-10
Representative	Kathy Castor	D	FL-11
Representative	Vern Buchanan	R	FL-13
Representative	Connie Mack	R	FL-14
Representative	Ileana Ros-Lehtinen	R	FL-18
Representative	Steve II Southerland	R	FL-2
Representative	Mario Diaz-Balart	R	FL-21
Representative	Allen B. West	R	FL-22
Representative	Sandy Adams	R	FL-24
Representative	David Rivera	R	FL-25
Representative	Richard B Nugent	R	FL–11
Representative	Gus M Bilirakis	R	FL–12
Representative	David Jolly	R	FL–13
Representative	Dennis A Ross	R	FL–15
Representative	Thomas J Rooney	R	FL–17
Representative	Patrick Murphy	D	FL–18

Representative	Trey Radel	R	FL−19
Representative	Alcee L Hastings	D	FL−20
Representative	Frederica S Wilson	D	FL−24
Representative	Carlos Curbelo	R	FL−26
Representative	Joe Garcia	D	FL−26
Representative	Ted S Yoho	R	FL−3
Representative	Corrine Brown	D	FL−5
Representative	John L Mica	R	FL−7
Representative	Alan Grayson	D	FL−9
Representative	Jack Kingston	R	GA-1
Representative	Paul C. Broun	R	GA-10
Representative	Phil Gingrey	R	GA-11
Representative	John Barrow	D	GA-12
Representative	Henry C. "Hank Johnson	[	GA-4
Representative	Tom Price	R	GA-6
Representative	Austin Scott	R	GA-8
Representative	Tom Graves	R	GA-9
Representative	Barry Loudermilk	R	GA−11
Representative	Sanford D Bishop	D	GA−2
Representative	Lynn A Westmoreland	R	GA−3
Representative	Rob Woodall	R	GA−7
Representative	Doug Collins	R	GA−9
Representative	Madeleine Z Bordallo	D	GU−At Large
Representative	Mazie K. Hirono	D	HI-2
Representative	Colleen W Hanabusa	D	HI−1
Representative	Mark Takai	D	HI−1
Representative	David Loebsack	D	IA-2
Representative	Steve King	R	IA-5
Representative	Bruce L Braley	D	IA−1
Representative	Rod Blum	R	IA−1
Representative	Adam Kinzinger	R	IL-11
Representative	Randy Hultgren	R	IL-14
Representative	Timothy V. Johnson	R	IL-15
Representative	Donald A. Manzullo	R	IL-16
Representative	Robert T. Schilling	R	IL-17
Representative	John Shimkus	R	IL-19
Representative	Jesse L. Jackson	D	IL-2
Representative	Joe Walsh	R	IL-8
Representative	Robert J. Dold	R	IL−10
Representative	Rodney Davis	R	IL−13
Representative	Aaron Schock	R	IL−18
Representative	Peter J Roskam	R	IL−6
Representative	Joe Donnelly	D	IN-2
Representative	Todd Rokita	R	IN-4
Representative	Dan Burton	R	IN-5
Representative	Mike Pence	R	IN-6
Representative	Marlin A Stutzman	R	IN−3
Representative	Tim Huelskamp	R	KS-1
Representative	Lynn Jenkins	R	KS-2
Representative	Kevin Yoder	R	KS-3
Representative	Mike Pompeo	R	KS-4
Representative	Ed Whitfield	R	KY-1
Representative	Brett Guthrie	R	KY-2
Representative	Geoff Davis	R	KY-4
Representative	Harold Rogers	R	KY-5
Representative	Ben Chandler	D	KY-6
Representative	Thomas Massie	R	KY−4
Representative	Andy Barr	R	KY−6
Representative	Steve Scalise	R	LA-1
Representative	Charles W. Boustany	R	LA-3
Representative	Jeffrey M. Landry	R	LA-3
Representative	Vance M McAllister	R	LA−5
Representative	Andy Harris	R	MD-1
Representative	C. A. Dutch Ruppersberger	D	MD-2
Representative	Roscoe G. Bartlett	R	MD-6

Representative	Dan Benishek	R	MI-1
Representative	Thaddeus G. McCotter	R	MI-11
Representative	Bill Huizenga	R	MI-2
Representative	Dave Camp	R	MI-4
Representative	Fred Upton	R	MI-6
Representative	Tim Walberg	R	MI-7
Representative	Candice S Miller	R	MI−10
Representative	Kerry L Bentivolio	R	MI−11
Representative	John R. Moolenaar	R	MI−4
Representative	Mike Bishop	R	MI−8
Representative	Mike J Rogers	R	MI−8
Representative	John Kline	R	MN-2
Representative	Michele Bachmann	R	MN-6
Representative	Chip Cravaack	R	MN-8
Representative	Tom Emmer	R	MN−6
Representative	Collin C Peterson	D	MN−7
Representative	Wm. Lacy Clay	D	MO-1
Representative	W. Todd Akin	R	MO-2
Representative	Sam Graves	R	MO-6
Representative	Billy Long	R	MO-7
Representative	Blaine Luetkemeyer	R	MO-9
Representative	Emanuel Cleaver	D	MO−5
Representative	Jason T Smith	R	MO−8
Representative	Bennie G. Thompson	D	MS−2
Representative	Steven M Palazzo	R	MS−4
Representative	Ryan K. Zinke	R	MT−At L
Representative	Steve Daines	R	MT−At Large
Representative	Heath Shuler	D	NC-11
Representative	Brad Miller	D	NC-13
Representative	Virginia Foxx	R	NC-5
Representative	Howard Coble	R	NC-6
Representative	Mike McIntyre	D	NC-7
Representative	Larry Kissell	D	NC-8
Representative	Sue Wilkins Myrick	R	NC-9
Representative	Patrick T McHenry	R	NC−10
Representative	Mark Meadows	R	NC−11
Representative	George Holding	R	NC−13
Representative	Renee L Ellmers	R	NC−2
Representative	Walter B Jones	R	NC−3
Representative	Mark Walker	R	NC−6
Representative	David Rouzer	R	NC−7
Representative	Richard Hudson	R	NC−8
Representative	Robert Pittenger	R	NC−9
Representative	Kevin Cramer	R	ND−At Large
Representative	Jeff Fortenberry	R	NE-1
Representative	Lee Terry	R	NE-2
Representative	Frank C. Guinta	R	NH-1
Representative	Charles F. Bass	R	NH-2
Representative	Jon Runyan	R	NJ-3
Representative	Bill Pascrell	D	NJ-8
Representative	Steven R. Rothman	D	NJ-9
Representative	Rodney P Frelinghuysen	R	NJ−11
Representative	Stevan Pearce	R	NM-2
Representative	Shelley Berkley	D	NV-1
Representative	Dina Titus	D	NV−1
Representative	Mark E Amodei	R	NV−2
Representative	Joseph J Heck	R	NV−3
Representative	Steven A Horsford	D	NV−4
Representative	Edolphus Towns	D	NY-10
Representative	Charles B. Rangel	D	NY-15
Representative	Nan A. S. Hayworth	R	NY-19
Representative	Steve Israel	D	NY-2
Representative	Richard L. Hanna	R	NY-24
Representative	Ann Marie Buerkle	R	NY-25

Representative	Tom Reed	R	NY-29
Representative	Gary L. Ackerman	D	NY-5
Representative	Robert L. Turner	R	NY-9
Representative	Timothy H Bishop	D	NY–1
Representative	Michael G Grimm	R	NY–11
Representative	Christopher P Gibson	R	NY–19
Representative	Peter T King	R	NY–2
Representative	William L Owens	D	NY–21
Representative	John Katko	R	NY–24
Representative	Chris Collins	R	NY–27
Representative	Steve Stivers	R	OH-15
Representative	Tim Ryan	D	OH-17
Representative	Bob Gibbs	R	OH-18
Representative	Jean Schmidt	R	OH-2
Representative	Jim Jordan	R	OH-4
Representative	Bill Johnson	R	OH-6
Representative	Steve Austria	R	OH-7
Representative	Steve Chabot	R	OH–1
Representative	Michael R Turner	R	OH–10
Representative	James B Renacci	R	OH–16
Representative	Brad R. Wenstrup	R	OH–2
Representative	John Sullivan	R	OK-1
Representative	Dan Boren	D	OK-2
Representative	Tom Cole	R	OK-4
Representative	Markwayne Mullin	R	OK–2
Representative	David Wu	D	OR-1
Representative	Greg Walden	R	OR-2
Representative	Kurt Schrader	D	OR-5
Representative	Tom Marino	R	PA-10
Representative	Lou Barletta	R	PA-11
Representative	Mark S. Critz	D	PA-12
Representative	Tim Holden	D	PA-17
Representative	Tim Murphy	R	PA-18
Representative	Mike Kelly	R	PA-3
Representative	Jason Altmire	D	PA-4
Representative	Glenn Thompson	R	PA-5
Representative	Patrick Meehan	R	PA-7
Representative	Michael G. Fitzpatrick	R	PA-8
Representative	Bill Shuster	R	PA-9
Representative	Robert A Brady	D	PA–1
Representative	Keith J Rothfus	R	PA–12
Representative	Charles W Dent	R	PA–15
Representative	Scott Perry	R	PA–4
Representative	James R. Langevin	D	RI-2
Representative	Tim Scott	R	SC-1
Representative	Joe Wilson	R	SC-2
Representative	Jeff Duncan	R	SC-3
Representative	Trey Gowdy	R	SC-4
Representative	Mick Mulvaney	R	SC-5
Representative	Tom Rice	R	SC–7
Representative	Scott DesJarlais	R	TN-4
Representative	Jim Cooper	D	TN-5
Representative	Marsha Blackburn	R	TN-7
Representative	Stephen Lee Fincher	R	TN-8
Representative	David P Roe	R	TN–1
Representative	Charles J Fleischmann	R	TN–3
Representative	Diane Black	R	TN–6
Representative	Louie Gohmert	R	TX-1
Representative	Michael T. McCaul	R	TX-10
Representative	Michael Conaway	R	TX-11
Representative	Ron Paul	R	TX-14
Representative	Ruben Hinojosa	D	TX-15
Representative	Bill Flores	R	TX-17
Representative	Randy Neugebauer	R	TX-19

Representative	Ted Poe	R	TX-2
Representative	Pete Olson	R	TX-22
Representative	Francisco "Quico" Canseco	R	TX-23
Representative	Kenny Marchant	R	TX-24
Representative	Blake Farenthold	R	TX-27
Representative	Henry Cuellar	D	TX-28
Representative	Sam Johnson	R	TX-3
Representative	Eddie Bernice Johnson	D	TX-30
Representative	Pete Sessions	R	TX-32
Representative	Randy K.Weber	R	TX−14
Representative	Will Hurd	R	TX−23
Representative	Roger Williams	R	TX−25
Representative	John R Carter	R	TX−31
Representative	Steve Stockman	R	TX−36
Representative	Ralph M Hall	R	TX−4
Representative	E. Scott Rigell	R	VA-2
Representative	Randy Forbes	R	VA-4
Representative	Robert Hurt	R	VA-5
Representative	Bob Goodlatte	R	VA-6
Representative	Morgan Griffith	R	VA-9
Representative	Robert J Wittman	R	VA−1
Representative	Dave Brat	R	VA−7
Representative	Dan Newhouse	R	WA−4
Representative	James Sensenbrenner	R	WI-5
Representative	Thomas E Petri	R	WI−6
Representative	Sean P Duffy	R	WI−7
Representative	Reid J Ribble	R	WI−8
Representative	David B. McKinley	R	WV-1
Representative	Shelley Moore Capito	R	WV-2
Representative	Alexander X. Mooney	R	WV−2
Representative	Nick J Rahall	D	WV−3
Representative	Cynthia M Lummis	R	WY−At Large
Senator	Tom Cotton	R	Arkansas
Senator	John Boozman	R	Arkansas
Senator	Cory Gardner	R	Colorado
Senator	Marco Rubio	R	Florida
Senator	Bill Nelson	D	Florida
Senator	Saxby Chambliss	R	Georgia
Senator	Mazie Hirono	D	Hawaii
Senator	Brian Schatz	D	Hawaii
Senator	Joe Donnelly	D	Indiana
Senator	Jerry Moran	R	Kansas
Senator	David Vitter	R	Louisiana
Senator	Mary Landrieu	D	Louisiana
Senator	John Walsh	D	Montana
Senator	Jon Tester	D	Montana
Seantor	Ben Nelson	D	Nebraska
Senator	Dean Heller	R	Nevada
Senator	Kelly Ayotte	R	New Hampshire
Senator	Bob Menendez	D	New Jersey
Senator	Thom Tillis	R	North Carolina
Senator	Jim Inhofe	R	Oklahoma
Senator	Pat Toomey	R	Pennsylvania
Senator	Bob Casey, Jr.	D	Pennsylvania
Senator	Tim Scott	R	South Carolina
Senator	Lindsey Graham	R	South Carolina
Senator	Lamar Alexander	R	Tennessee
Senator	Joe Manchin	D	West Virginia

LETTERS FROM MEMBERS OF CONGRESS TO EXECUTIVE BRANCH OFFICIALS

Congress of the United States
Washington, DC 20515

August 3, 2010

Dr. Margaret A. Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Dr. Hamburg:

As Members of Congress who represent cigar manufacturers and retailers, we write today to highlight the premium cigar industry, and especially its unique history, culture and economic impact on the United States. **As you develop new regulations for tobacco, we urge you to distinguish premium cigars from other, more harmful, types of tobacco products.**

It has been one year since the signing of The Family Smoking Prevention and Tobacco Control Act (Tobacco Act), which provides the Food and Drug Administration (FDA) with new authority to regulate "tobacco products." We commend FDA's efforts in promoting the primary purpose of the Tobacco Act: the protection of America's youth using the best available science. In particular, we appreciate FDA's efforts to ban flavored cigarettes, re-issue the final 1996 Regulation Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Children and Adolescents, and establish the Tobacco Products Scientific Advisory Committee.

However, as you develop these new regulations, we wish to emphasize important differences between premium cigars and the types of products explicitly subject to the Tobacco Act. Premium cigars are intended for use and enjoyment by adults, and are not used by adolescents. Second, premium cigars are essentially crafted by hand and often take five years or more. In contrast to mass produced cigarettes, the manufacture of a premium cigar is more like the manufacture of a fine wine, making the marketing and subsequent sale of premium cigars entirely different from cigarettes or other types of tobacco.

It is also important to note that, the vast majority of cigar smokers enjoy cigars only occasionally and often as a celebratory product enjoyed in a social setting. Premium cigars are a niche market with a distinct adult consumer base. In fact, they represent less than one-half of 1% of the overall tobacco market. These usage differences cause premium cigars to pose a substantially different and lower health risk than those risks associated with other tobacco products. Lastly, premium cigars are sold almost exclusively in specialty tobacco shops, not in gas stations or convenience stores, further restricting potential access for minors. That being said, restrictive regulations on the premium cigars would adversely affect thousands of small and family-owned businesses throughout the country who often deal exclusively in premium cigars.

The concern about widespread cigarette dependence and youth access simply do not apply to a discussion about premium cigars which is why Congress focused on cigarettes rather than premium cigars in the Tobacco Act. It is vital for the FDA to keep this important

distinction in mind as it implements the Tobacco Act. Regulations that may be appropriate for large cigarette manufacturers would have a tremendously adverse effect on the premium cigar industry. Accordingly, should the FDA propose to make the Tobacco Act applicable to cigars, we urge the FDA to create an exemption for premium cigars.

Should you have any questions on this matter, please do not hesitate to contact Caitrin McCarron with Congressman Tom Cole's office at caitrin.mccarron@mail.house.gov or (202) 225-6165or Yelena Vaynberg with Congressman John Kline's office at yelena.vaynberg@mail.house.gov or (202) 225-2271. Thank you for your attention to this matter.

Sincerely,

Tom Cole
Member of Congress

John Kline
Member of Congress

Nick J. Rahall
Member of Congress

Alan Grayson
Member of Congress

Marsha Blackburn
Member of Congress

Lynn Westmoreland
Member of Congress

Jim Cooper
Member of Congress

Lincoln Diaz-Balart
Member of Congress

Fred Upton
Member of Congress

Sue Myrick
Member of Congress

Bill Posey
Member of Congress

Cc: Lawrence R. Deyton, M.S.P.H., M.D., Director, Center for Tobacco Products, Food and Drug Administration

United States Senate
WASHINGTON, DC 20510-0905

BILL NELSON
FLORIDA

August 16, 2010

Dr. Margaret A. Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Dr. Hamburg:

I write today to highlight the premium cigar industry, and especially its unique history, culture and economic impact on the United States. As you develop new regulations for tobacco, I urge you to distinguish premium cigars from other, more harmful, types of tobacco products.

It has been one year since the signing of The Family Smoking Prevention and Tobacco Control Act (Tobacco Act), which provides the Food and Drug Administration (FDA) with new authority to regulate "tobacco products." I commend FDA's efforts in promoting the primary purpose of the Tobacco Act: the protection of America's youth using the best available science. In particular, I appreciate FDA's efforts to ban flavored cigarettes, re-issue the final 1996 Regulation Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Children and Adolescents, and establish the Tobacco Products Scientific Advisory Committee.

However, as you develop these new regulations, I wish to emphasize important differences between premium cigars and the types of products explicitly subject to the Tobacco Act. Premium cigars are generally more expensive than mass produced tobacco products and are sold almost exclusively at specialty tobacco shops, making them significantly less likely to be used by adolescents. Also, premium cigars do not introduce as much nicotine into the body as cigarettes and are thus less likely to become habit forming.

It is also important to note that the vast majority of cigar smokers enjoy cigars only occasionally and often as a celebratory product enjoyed in a social setting. Premium cigars are a niche market with a distinct adult consumer base. In fact, they represent less than one-half of 1% of the overall tobacco market. These usage differences cause premium cigars to pose a substantially lower public health risk than other tobacco products. Restrictive regulations on the premium cigars would adversely affect thousands of small and family-owned businesses

throughout the country and negatively impact the cultural heritage of Florida and the Nation, with minimal benefit to public health.

The concern about widespread cigarette dependence and youth access simply does not apply to a discussion about premium cigars, which is why Congress focused on cigarettes rather than premium cigars in the Tobacco Act. It is vital for the FDA to keep this important distinction in mind as it implements the Tobacco Act. Regulations that may be appropriate for large cigarette manufacturers would have a tremendously adverse effect on the premium cigar industry. Accordingly, should the FDA propose to make the Tobacco Act applicable to cigars, we urge the FDA to create an exemption for premium cigars.

Thank you for your attention to this matter.

Sincerely,

Bill Nelson

KATHY CASTOR
11TH DISTRICT, FLORIDA

COMMITTEE ON
ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH
SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION
SUBCOMMITTEE ON COMMUNICATIONS, TECHNOLOGY, AND THE INTERNET

COMMITTEE ON
STANDARDS OF OFFICIAL CONDUCT

DEMOCRATIC STEERING AND
POLICY COMMITTEE

REGIONAL WHIP

Congress of the United States
House of Representatives
Washington, DC 20515–0911

WASHINGTON OFFICE:
317 CANNON BUILDING
WASHINGTON, DC 20515
(202) 225-3376

DISTRICT OFFICE:
4144 NORTH ARMENIA AVENUE
SUITE 300
TAMPA, FL 33607
(813) 871-2817

www.castor.house.gov

August 19, 2010

Dr. Margaret A. Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Springs, MD 20993

RE: Premium Cigars and the Tobacco Act

Dear Commissioner Hamburg:

I am writing to follow up on our discussion about premium cigars, their unique history and culture, and their economic impact on my community. As you develop new regulations for tobacco, I urge you to distinguish premium cigars from other types of tobacco products explicitly covered in the Family Smoking Prevention and Tobacco Control Act (the Tobacco Act).

As you know, the Tobacco Act provides the Food and Drug Administration (FDA) with new authority to regulate tobacco products. I commend the FDA's efforts in promoting the primary purpose of the Tobacco Act – protecting America's youth. In particular, I appreciate the FDA's efforts to ban flavored cigarettes, re-issue the final 1996 Regulation Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Children and Adolescents, and establish the Tobacco Products Scientific Advisory Committee.

As you develop these new regulations, I wish to emphasize important differences between premium cigars and the types of products explicitly subject to the Tobacco Act. Premium cigars are intended for use and enjoyment by adults, and for a variety of reasons, are not used by adolescents or children. In contrast to mass produced cigarettes, the manufacture of a premium cigar ensures the marketing and subsequent sale of premium cigars is different from cigarettes or other types of tobacco. Premium cigars are crafted by hand and often take five years or more to produce, increasing the price to the consumer. Children and adolescents are less likely to be able to pay premium prices for cigars.

It is also important to note that the majority of cigar smokers smoke cigars occasionally and often as a product enjoyed in a social setting. Premium cigars are a niche market with a distinctly adult consumer base, representing less than half of one percent over the overall tobacco market. Premium cigars are sold almost exclusively in specialty tobacco shops that are often family owned and operated, as is the case in my district, not in gas stations or convenience stores. The owners, manning the counter of their shop, restrict potential access for minors. Premium cigars are also not mass-marketed and are marketed without the practices used in the cigarette industry that promote purchases by children. Regulations on premium cigars would adversely affect thousands of small and family-owned businesses throughout the country and in my district. These "mom and pop" businesses often deal exclusively in premium cigars, staff their counters, and subject all sales to a high level of scrutiny.

As a result of the culture, history, ownership of the shops that sell cigars, and the distinct difference in marketing, the concern about widespread youth access does not apply to premium cigars. I believe this is why Congress focused on cigarettes rather than on premium cigars in the Tobacco Act. It is important for the FDA to keep this important distinction in mind as it implements the Tobacco Act. Regulation that may be appropriate for large cigarette manufacturers would have a tremendously adverse effect on the premium cigar business. Accordingly, should the FDA propose to make the Tobacco Act applicable to cigars, the FDA should consider an exemption for premium cigars.

Finally, I urge you to be vigilant and thorough in your targeting of cigarette companies that overtly and covertly target their marketing towards children and teenagers. This is one of the most important health issues of our day. I am confident in your leadership as you tackle this serious public health concern.

Sincerely,

Kathy Castor

Kathy Castor
United States Representative
Florida District 11

RANKING MEMBER:
COMMITTEE ON FOREIGN AFFAIRS

http://foreignaffairs.house.gov/minority/republicans.htm
www.twitter.com/irl
www.youtube.com/ileanaroslehtinen

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MIAMI BEACH AREAS:
(305) 934-9441

Congress of the United States
House of Representatives

ILEANA ROS-LEHTINEN
18TH DISTRICT, FLORIDA

October 6, 2010

Dr. Margaret A. Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Dr. Hamburg:

I am writing to ask that as the FDA develops new regulations governing tobacco, it should distinguish premium cigars from other types of tobacco products.

Premium cigar retailers and manufacturers in Florida have stated that the premium cigar industry is different from the rest of the tobacco industry. Largely comprised of small, family-owned and operated premium tobacco shops, the premium cigar industry possesses its own storied history, culture, and niche market of adult consumers.

Premium cigar manufacturers and retailers comprise less than one-half of 1% of the overall tobacco market. The vast majority of premium cigars are sold by neighborhood tobacconists who personally man their stores. These retailers do not pander or sell their products to minors and premium cigar prices virtually eliminates significant use by underage consumers. Premium cigars are designed and advertised as unique artisan products for adult use only.

Premium cigars are not inhaled and are smoked in moderation. Consequently, premium cigars pose substantially different, and lower, health risks compared with other tobacco products. Aware of these differences, Congress did not focus on premium cigars in The Family Smoking Prevention and Tobacco Control Act (Tobacco Act).

I commend the FDA for its efforts to enforce the Tobacco Act and protect America's youth from underage tobacco use.

Sincerely,

Ileana Ros-Lehtinen
Member of Congress

IRL:joc

CHARLES W. BOUSTANY, JR., MD
7TH DISTRICT, LOUISIANA

LAFAYETTE DISTRICT OFFICE:
800 LAFAYETTE STREET
SUITE 1400
LAFAYETTE, LA 70501
(337) 235-6322

LAKE CHARLES DISTRICT OFFICE:
ONE LAKESHORE DRIVE
SUITE 1775
LAKE CHARLES, LA 70629
(337) 433-1747

COMMITTEE ON WAYS AND MEANS
SUBCOMMITTEES:
OVERSIGHT, *RANKING MEMBER*
INCOME SECURITY AND FAMILY SUPPORT

WASHINGTON, DC OFFICE:
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WASHINGTON, DC 20515
(202) 225-2031

Congress of the United States

House of Representatives

Washington, DC 20515–0304

October 12, 2010

Dr. Margaret A. Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Dr. Hamburg:

I write today to ask you to consider differences between premium cigars and other types of tobacco products as the FDA considers regulations governing tobacco.

Premium cigar retailers and manufacturers are composed of small, family-owned and operated premium tobacco shops that serve a niche market of adult consumers. These businesses comprise less than one-half of 1 percent of the overall tobacco market. The price commanded by premium cigars virtually eliminates significant use by children or underage consumers.

It is my understanding that Congress focused primarily on other forms of tobacco when drafting the Family Smoking and Tobacco Control Act. Accordingly, should the FDA propose to make the Tobacco Act applicable to cigars, I urge the FDA to exempt premium cigars.

Sincerely,

Charles W. Boustany, Jr., M.D.
Member of Congress

GEORGE S. LeMIEUX
FLORIDA

COMMITTEES:
ARMED SERVICES
COMMERCE, SCIENCE AND TRANSPORTATION
SPECIAL COMMITTEE ON AGING

United States Senate
WASHINGTON, DC 20510–0907

December 1, 2010

Dr. Margaret A. Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD. 20093

Dear Dr. Hamburg,

I write today to urge you to differentiate premium cigars from other types of tobacco products as you promulgate new regulations for tobacco under The Family Smoking Prevention and Tobacco Control Act (Tobacco Act).

It has come to my attention that the original intent of the Tobacco Act, the protection of youth from the harmful effects of tobacco through heightened Food and Drug Administration (FDA) regulatory authority, could be misinterpreted to treat premium cigars equivalently to more harmful and youth-targeted tobacco products such as traditional and flavored cigarettes. Given the differences in proven heath risks between premium cigars and these products, coupled with the relatively small market share premium cigars represent within the overall tobacco market, it is important to distinguish the two products clearly when developing new regulations.

Further, I have spoken with small business owners who claim that the restrictive regulation of premium cigars as cigarettes would result in adverse and potentially irrevocable implications for their small businesses. These businesses market and sell premium cigars to an exclusively adult consumer base. It would seem that imposing mistakenly targeted regulations on these small businesses would not result in decreased youth nicotine addiction.

Congress understood the need to limit youth exposure to tobacco products to combat addictiveness and accordingly passed the Tobacco Act. The intent was clear: to limit youth access to cigarettes, not restrict the adult use of premium cigar products. I urge the FDA to recognize Congress' intent when developing these new regulations and seek to protect the health of America's youth, not burden a largely niche industry during already difficult economic times.

Should you have any questions or concerns, please do not hesitate to contact Frank Walker on my staff at (202) 228-5953. I appreciate your prompt consideration of this request.

Sincerely,

George S. LeMieux
United States Senator

GSL/fcw

Congress of the United States
Washington, DC 20515

December 20, 2010

Dr. Margaret A. Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Dr. Hamburg:

I write today to highlight issues concerning the premium cigar industry, and urging that, as you develop new regulations for tobacco, you distinguish premium cigars from other, more harmful types of tobacco products.

I commend FDA's efforts in promoting the primary purpose of the Tobacco Act, which is the cessation of youth smoking using the best available science. Efforts to ban flavored cigarettes, regulation of smokeless tobacco, and establishment of the Tobacco Products Scientific Advisory Committee, will go a long way toward protecting youth from the perils of smoking.

However, I want to emphasize the major differences that exist between premium cigars and the types of products that were targeted by the Tobacco Act. Premium cigars are generally more expensive than mass produced tobacco products and sold at specialty retail shops. As such, they are far less likely to be accessible and convenient for adolescents to purchase. Scientifically speaking, premium cigars are far less habit-forming as they introduce significantly less nicotine into the system.

The vast majority cigar smokers enjoy them only recreationally as a celebratory product or in specific social settings. These cigars are a niche market geared toward an adult consumer base. As such, the premium cigar industry represents less than one-half percent of the overall tobacco market, representing a significant small public health risk. It is my opinion that these relatively small adverse effects are greatly outweighed by the effects on the many small, family businesses of regulating these products under the new FDA rules.

It is vital for the FDA to keep these important distinctions in mind as it implements the Tobacco Act. Regulations that may be appropriate for cigarette manufacturers and small cigars would

have a tremendously adverse effect on the premium cigar industry. I strongly urge that any regulations affecting the cigar industry exempt this special niche of cigar manufacturers.

Thank you for your attention to this matter.

Sincerely,

KENDRICK B. MEEK

BOB CORKER
TENNESSEE
http://www.corker.senate.gov/

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WASHINGTON, DC 20510
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United States Senate

COMMITTEES:
BANKING, HOUSING AND URBAN AFFAIRS
FOREIGN RELATIONS
ENERGY AND NATURAL RESOURCES
SPECIAL COMMITTEE ON AGING

March 21, 2011

Dr. Margaret A. Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Dr. Hamburg:

As a Member of Congress who represents premium cigar manufacturers and retailers, I have heard numerous concerns from constituents regarding the potential regulation of premium cigars under the Tobacco Act that FDA continues to implement. Despite the fundamental differences between premium cigars and other tobacco products, premium cigars have not always been adequately differentiated from more prevalent, mass-produced forms of tobacco, such as cigarettes. As the FDA considers future regulations governing tobacco products, I urge you to distinguish premium cigars from the more harmful tobacco products.

Last year's passage of The Family Smoking Prevention and Tobacco Control Act (Tobacco Act) strengthened the FDA's ability to provide meaningful oversight over the tobacco industry. I appreciate the FDA's efforts since then to implement the Act's various provisions, especially its commitment to reducing underage tobacco use. However, regulations that may be appropriate for large cigarette manufacturers may not be suitable for the premium cigar industry because they are not appealing to minors, have different health effects and product characteristics, and are manufactured and sold primarily by small businesses.

Premium cigars are labor-intensive, artisan products that are designed for use and enjoyment by adults. In addition, manufacturers and retailers of premium cigars occupy their own business and cultural niche, with sales comprising less than one-half of 1% of the overall tobacco market. The unique tradition of premium cigars is also reflected in the manner in which premium cigars are enjoyed. Premium cigars are typically not inhaled and are smoked in moderation, with the majority of cigar smokers being "occasional" users. As a result, premium cigars pose substantially different health risks compared with other tobacco products.

As mentioned above, I urge the FDA to recognize the fundamental differences between premium cigars and other tobacco products as new regulations of the Tobacco Bill are considered. I appreciate your attention to this important matter.

Sincerely,

Bob Corker
United States Senator

United States Senate
WASHINGTON, DC 20510

March 28, 2011

Dr. Margaret A. Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Commissioner Hamburg:

As Members of Congress who represent premium cigar manufacturers and retailers, we wanted to bring to your attention the unique nature of the premium cigar industry, including its distinctive culture, artisan tradition, and business model. Despite the vast differences between premium cigars and other tobacco products, premium cigars have not always been adequately differentiated from more prevalent, mass-produced forms of tobacco, such as cigarettes. As the FDA considers future regulations governing tobacco products, we believe it should recognize the fundamental differences between premium cigars and other types of tobacco products.

Last year's passage of The Family Smoking Prevention and Tobacco Control Act (Tobacco Act) strengthened the FDA's ability to provide meaningful oversight over the tobacco industry. We appreciate the FDA's efforts since then to implement the Act's various provisions, especially its commitment to reducing underage tobacco use. However, as the FDA develops new regulations to advance the Tobacco Act's objectives, we urge it to distinguish premium cigars from other tobacco products that Congress determined should be first subject to the Act's provisions.

Premium cigar manufacturers and retailers occupy their own business and cultural niche, with sales comprising less than one-half of 1% of the overall tobacco market. As labor-intensive, artisan products, premium cigars are designed for use and enjoyment by adults

As one might expect, the unique tradition of premium cigars is also reflected in the manner in which premium cigars are enjoyed. Premium cigars are not inhaled, and are smoked in moderation, with the majority of cigar smokers being "occasional" users. As a result, premium cigars pose substantially different health risks compared with other tobacco products.

As the FDA continues to implement the Tobacco Act, we urge it to recognize the fundamental differences between premium cigars and other tobacco products. Regulations that may be appropriate for large cigarette manufacturers are not suitable for the premium cigar industry in that premium cigars are not appealing to minors, have different health effects and product characteristics, and are manufactured and sold primarily by small businesses. Accordingly, should the FDA propose to make the Tobacco Act applicable to cigars, we urge the FDA to exempt premium cigars

Sincerely,

Saxby Chambliss

Lamar Alexander

United States Senate

WASHINGTON, DC 20510

May 23, 2013

Dr. Margaret A. Hamburg
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Commissioner Hamburg:

I want to bring to your attention concerns that have been conveyed to me by professional retail tobacconists, as well as consumers and manufacturers of premium cigars.

Premium cigars have an especially unique history, culture and economic impact within the United States and in the cigar producing nations of Latin America. As you develop new regulations for tobacco, I urge you to consider the unique nature of premium cigars.

I commend FDA's efforts in promoting the primary purpose of The Family Smoking Prevention and Tobacco Control Act. Your work in protecting America's youth using the best available science and various public awareness campaigns is commendable. However, premium cigars are generally more expensive than other tobacco products and are sold almost exclusively at specialty tobacco shops, making them less likely to be used by adolescents. Premium cigars are a niche market and have a distinct adult consumer base. They are often enjoyed only occasionally, and usually as a celebratory product.

I hope you will take these and related considerations into account as you approach further implementation.

Sincerely,

Mark R Warner

MARK R. WARNER
United States Senator

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11TH DISTRICT, VIRGINIA
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(703) 670-4989

Congress of the United States
House of Representatives
Washington, DC 20515-4611

July 19, 2013

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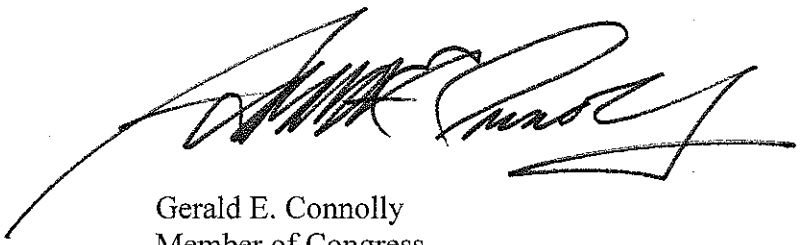
Dr. Margaret A. Hamburg
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0001

Dear Commissioner Hamburg,

I commend your efforts to effectively implement the Family Smoking Prevention and Tobacco Control Act. During my nearly five years in Congress, I have been incredibly proud to support a number of initiatives to prevent tobacco use among children, make vital investments in tobacco prevention and cessation programs, and raise the cigarette tax to finance expanded health care coverage under the State Children's Health Insurance Program (SCHIP).

I am writing to convey concerns that have been brought to me by professional retail tobacconists in my district. As you develop new regulations for the use of tobacco, I ask that you consider the unique nature of premium cigars. Premium cigars are generally sold at specialty shops and are more expensive than other tobacco products, making them less likely to be used by children. They are often enjoyed only occasionally and are a niche market. Again, I applaud your efforts to promote the primary purpose of the Family Smoking Prevention and Tobacco Control Act and hope that you will take these concerns into consideration as you implement the legislation.

Sincerely,



Gerald E. Connolly
Member of Congress
11th District, Virginia

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Joe Courtney
Congress of the United States
2nd District, Connecticut

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F (860) 886-2974

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F (860) 741-6036

March 20, 2014

The Honorable Tom Vilsack
Secretary of Agriculture
U.S. Department of Agriculture
1400 Independence Avenue, SW
Washington, DC 20250

Dear Secretary Vilsack:

It is my understanding that the U.S. Food & Drug Administration (FDA) is preparing to exercise its authority under The Family Smoking Prevention and Tobacco Control Act to issue regulations deeming other "tobacco products." Currently awaiting consideration by the Office of Management and Budget, this regulation is expected to apply to products such as cigars, e-cigarettes, certain dissolvable tobacco products, pipe tobacco, and hookah. I write with specific concerns over the regulation's impact on premium cigars.

While I understand that FDA has included premium cigars in its deeming regulation, I believe that this goes beyond congressional intent of the Tobacco Control Act. There is an important distinction that must be made between the premium cigar market and that of the cigarillo or small-mass produced cigars. By regulating premium cigars as if they were cigarettes, cigarillos, or smokeless tobacco, the FDA would ignore the fundamental differences between premium cigars and other tobacco products. Premium cigars are not marketed for children, and there is no evidence that children or adolescents smoke premium cigars. Comprising less than one half of one percent of the overall tobacco market, premium cigars are a niche market with significant price points targeted to a distinct adult consumer base.

The Connecticut River Valley has been growing tobacco reaching back before the birth of our nation. Today, the shade tobacco produced in this area is considered one of the finest cigar wrappers in the world. Production is spread over roughly a hundred family farms and is a significant economic driver in our state's agricultural economy. The labor-intensive process employs an estimated 5,000 seasonal workers and requires a range of ancillary services related to fuel, fertilizer, and equipment parts and maintenance. I am greatly concerned that the FDA's actions would have a significant economic impact on our state.

Before FDA moves ahead, I feel that it is important that the agency take a thorough look at this issue, particularly from an economic perspective. For that reason, I request that the USDA

conduct an economic impact analysis of the potential impact on family tobacco farms, related support industries, taxes, and other relevant components in Connecticut resulting from the FDA's proposed regulation.

I greatly appreciate your attention in this matter and look forward to your response.

Sincerely,

Joe Courtney
Member of Congress

DON YOUNG
CONGRESSMAN FOR ALL ALASKA
WASHINGTON OFFICE:
2314 RAYBURN BUILDING
WASHINGTON, DC 20515
202–225–5765

COMMITTEE ON
NATURAL RESOURCES

CHAIRMAN, SUBCOMMITTEE ON
INDIAN AND ALASKA NATIVE AFFAIRS

COMMITTEE ON
TRANSPORTATION & INFRASTRUCTURE

REPUBLICAN
POLICY COMMITTEE

Congress of the United States
House of Representatives
Washington, D.C. 20515

2014 JUL 24 P 1:12

July 21, 2014

Margaret Hamburg, Commissioner
Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RIN: 0910-AG38

Commissioner Hamburg,

I write to provide comments to the Federal Drug Administration's (FDA) Center for Tobacco Products (CTP) proposed rule to deem additional tobacco products subject to regulation under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). (Docket FDA-2014-N-0189-0001).

As detailed in the opening pages of the legislative text, Congress found youth access to tobacco products and the health effects of addiction to tobacco products to be a compelling issue for our nation. Those are the issues the Act sought to address. Neither of those concerns applies to premium cigars, products which are enjoyed in moderation by adult consumers. I believe that improper application of the FDA's authority would result in the loss of thousands of American jobs, tens of thousands of jobs around the world, limit consumer freedom, and unnecessarily detract from the FDA's ability to accomplish the goals Congress intended. During Committee consideration of the legislation, as well as ultimately the debate on the House floor, premium cigars were not raised as an issue.

I believe an alternative option proposed by the FDA, to exempt premium cigars, is consistent with Congress' intent in the law. However, in order to properly define a premium cigar, this alternative must be amended to exclude the price component qualifier of $10 for the following reasons:

- The price qualifier is predicated on the retail sales price, which manufacturers cannot control and would therefore have no way of knowing whether its products are subject to regulation until the product is ultimately sold.

- The $10 price qualifier fails to take into account different locales excise taxes, regional pricing schemes, and catalog sales.

I appreciate the efforts the FDA has made to understand the premium cigar industry, its products and consumers. The inclusion of "option 2" in the proposed rule is an indication of the

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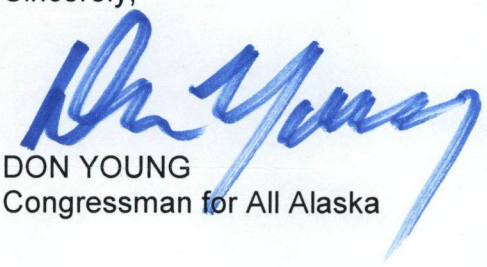
612 W. WILLOUGHBY AVENUE, SUITE B
P.O. BOX 21247
JUNEAU, ALASKA 99802
907–586–7400

CALL TOLL-FREE
1–866–990–5979

FDA's recognition that premium cigars are a unique product. I strongly urge the FDA to, in its final rule, proceed in that direction and modify definition of the category to be one that can be effectively implemented and provide certainty for manufacturers, retailers and consumers.

I appreciate your consideration of my comments.

Sincerely,



DON YOUNG
Congressman for All Alaska

KATHY CASTOR
14TH DISTRICT, FLORIDA

COMMITTEE ON
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SUBCOMMITTEE ON
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REGIONAL WHIP

Congress of the United States
House of Representatives
Washington, DC 20515–0914

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www.castor.house.gov

August 7, 2014

Margaret A. Hamburg
Commissioner
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Below you will find an analysis from a constituent of mine regarding the preservation of an historic landmark and functioning cigar factory within my district. My constituent believes that it will provide the Food and Drug Administration ("FDA") a new perspective on the unintended consequences we will face at home if new rules pursuant to the Family Smoking Prevention and Tobacco Control Act are not carefully crafted and considered.

Sincerely,

Kathy Castor

Kathy Castor
United States Representative
Florida – District 14

***

I would like to offer assistance to the *Office of U.S. Rep. Kathy Castor* (Julie) & *AIA-Tampa Bay Heritage Committee* (Kim) regarding any of the community initiatives/efforts that may relate towards preventing *HHS FDA 21 CFR Parts 1100, 1140 & 1143* from causing great damage to the historical integrity of the *Ybor City National Historic Landmark District & our Community* as a greater whole via the various regulations that would be imposed upon the *J.C. Newman Cigar Co.* & lead to the eventual closure of this historic company associated with the *District*.

Aside from providing some found information to the J.C. Newman Cigar Co. directly, I have been trying to help by taking the following actions between the last 2 days:

- Contacted the *White House's* special *Council* associated with *Environmental Quality*, per direction from both the *National Preservation Institute* & the *National Environmental Policy Act of 1969 (NEPA 1969)*.
    - Point of Contact given at the *White House Council on Environmental Quality* is the following individual:

- *Horst Greczmiel - Associate Director for NEPA Oversight*

- Reason for contacting Council on Environmental Quality is related to the information identified in red below.

- Preparing a statement to post via *Regulations.gov*. Statement will work to identify specific provisions from the following Federal Legislation/Documents that are potentially applicable to the matter

    - Potentially most useful piece of Federal Legislation/Documentation that I have currently come across includes the following:

        - *National Environmental Policy Act of 1969 (NEPA 1969)*

            - Issuing a special request to conduct another *Environmental Impact Assessment* to understand how proposed *Rule(s)* associated with *HHS FDA 21 CFR Parts 1100, 1140 & 1143*. Reason for request based on the initial *Assessment* not taking into consideration the affect the Rule(s) would have on preserving "important historic, cultural, and natural aspects of our national heritage" per *NEPA Sec. 101(b)*

            - Due to the "important historic" & "cultural" aspects of our "national heritage" existing within the *Ybor City National Historic Landmark District*, a *District* recognized on the *National Register of Historic Places* by both the *U.S. Department of the Interior* & its *National Park Service*; *NEPA Sections 2, 102, 103, 104*, in addition to *NEPA Section 101* in its entirety should be able to be used as a justified reason to conduct another *Environmental Impact Assessment* regarding the proposed *Rule(s)* identified above.

            - Important "historic" & "cultural" aspects found within the *District* that will be directly impacted by the proposed *Rule(s)* are both the "historic" *E. Regensberg & Sons Cigar Factory* & the various "historical resources" & the period specific practices that are maintained within the *Building* by the *J.C. Newman Cigar Co.* As specifically cited within the *NPS Registration Form* that was submitted to both the *U.S. Department of the Interior* & its *National Park Service* for *Ybor City's* acceptance as a *National Historic Landmark District* on the *National Registry of Historic Places*, the identification of the *Building* as being the *"only major Ybor City factory still manufacturing cigars"* was a relevant historical quality included within the *Form*. Also of national "historical" & "cultural importance" is *J.C. Newman Cigar Co.* is the last large-scale cigar factory in the U.S. producing cigars in a manner using historic, 1930's-era cigar manufacturing practices, much of which is completed by human means rather than an

automated process. Loosing this *Factory* would discontinue the 128 year history of Ybor City manufacturing the good which was the sole purpose of its intention as a 20th Century American Company Town.

- Other pieces of potentially relevant Federal Legislation
  - National Historic Preservation Act of 1966 (Amended in 2006)
  - Executive Order – 12866 | Regulatory Planning & Review (President Obama)
  - Executive Order – 13287 | Preserve America (President George W. Bush)
  - Executive Order – 13563 | Improving Regulation & Regulatory Review (President Clinton)
  - Executive Order – 11593 | Protection & Enhancement of the Cultural Environment (President Nixon)

- Contacted *Dr. Tim Parsons*, the *State of Florida's Historic Compliance & Review Director*. Contact was made to provide testimony & acknowledge concern. *Dr. Parsons* has said he will be available for Council regarding the situation & can assist in any way he can. He currently has investigated the matter & says there hasn't been a way he can see using *NHPA Section 106*.

- Contacted the Southeastern Regional Office associated with the National Park Service's National Historic Landmark Program. Left a message regarding the issue with the Office's Point of Contact. Response pending.

- Discussed the above with a Representative (Julie) from the *Office of U.S. Rep. Kathy Castor* regarding the information identified in red above.

I am happy to help you all with anything else that might advocate on behalf of this effort.

You can contact me either through using my contact information provided below.

As the Newman family, my family has also been here for four generations & we do not want to see this industry of primary historical importance to both the *District* & our Community *go away forever*. Many members of my family worked in the cigar industry, including my great-grand parents & many great aunts & uncles who defined their way of life through the means associated with Ybor City's core reason for existence - *an American Company Town that was developed by Vincent Martinez-Ybor for the primary purpose of producing the cigar*.

I will be looking forward to hearing from you both regarding your views associated with the above in the near future.

Matthew D. Suarez

DAVID W. JOLLY
13TH DISTRICT, FLORIDA

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Congress of the United States
House of Representatives
Washington, DC 20515–0913

August 7, 2014 2014 AUG -8 P 1:11

Margaret A. Hamburg
Commissioner
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Exempt Premium Cigars - Update "Premium Cigar" Definition - Food & Drug Administration, Docket No. FDA-2014-N-01 89, RIN 0910-AG38

Dear Dr. Hamburg:

Thank you for the opportunity to provide comments on the recently released U.S. Food and Drug Administration (FDA) proposed rule relating to tobacco products pursuant to the Family Smoking Prevention and Tobacco Control Act (the Act). I urge the FDA to adopt its proposed "Option 2" which exempts "premium cigars" from regulation, and amend the "Option 2" definition of "premium cigar".

The intent of the Act was to target tobacco products marketed to children and products which cause addiction. Premium cigars fall under neither of those categories. Premium cigars differ significantly from most other tobacco products because they are not mass-produced or sold in stores frequented by minors. They have established artisan traditions and a cultural niche. For example, premium cigars in Tampa are created through a process that blends "hand-crafting" and historically-significant early 20th century machines, producing refined products enjoyed by adults in moderation often at celebratory occasions. New regulations on premium cigars would impose considerable costs and unnecessary burdens on small "mom and pop" businesses throughout my community.

In the proposed rule, the FDA offers a option known as "Option 2" which would exempt premium cigars from the regulations for tobacco products which may appeal to children and which cause addiction. "Option 2" defines "premium cigars" as: wrapped in whole tobacco leaf; contain a 100 percent leaf tobacco binder; contain primarily long filler tobacco; are made by manually combining the wrapper, filler, and binder; have no filter, tip, or non-tobacco mouthpiece and are capped by hand; do not have a characterizing flavor other than tobacco; weigh more than six pounds per thousand units; and sell for $10 or more per cigar.

While I agree with the exemption for premium cigars, it is my hope that the definition be modified to eliminate the arbitrary $10 per cigar price point and include cigars rolled by hand-

operated, vintage cigar machines, like those in my community. I believe a more appropriate definition of a "premium cigar" would be the more logical and widely-accepted definition used in legislation currently before Congress:

a. Any roll of tobacco that is wrapped in 100 percent leaf tobacco, bunched with 100 percent tobacco filler, contains no filter, tip or non-tobacco mouthpiece, weighs at least 6 pounds per 1,000 count, and--

1. has a 100 percent leaf tobacco binder and is hand rolled;
2. has a 100 percent leaf tobacco binder and is made using human hands to lay the leaf tobacco wrapper or binder onto only one machine that bunches, wraps, and caps each individual cigar; or
3. has a homogenized tobacco leaf binder and is made in the United States using human hands to lay the 100 percent leaf tobacco wrapper onto only one machine that bunches, wraps, and caps each individual cigar; and

b. does not include a cigarette or a little cigar

The proposed $10 price-point is arbitrary and would shutter certain smaller companies, including some in my community. *Cigar Aficionado*, the leading magazine for premium cigar reviews, rated 608 premium cigars in 2013, and nearly 70 percent fell below $10 per cigar. About half of *Cigar Aficionado*'s top 25 cigars of 2013 were priced less than $10. Even the FDA's proposal acknowledges that 87 percent of premium, hand-made cigars sold on one well-known Internet site sell for less than $10. The definition of "premium cigar" would be better determined by the size of the cigar and tobacco leaf wrapper or binder and the use of some (but not limited to) hand-crafting.

I strongly support the intent of the Act to eliminate tobacco use among children; however this objective must be executed with reasonableness. There is no evidence that minors consume premium cigars or that these products have any youth appeal. FDA should follow the stated legislative intent of the Act and target products marketed to children and which cause addiction.

Thank you for your attention to this important matter not only in my district but throughout the country. I appreciate the opportunity to offer my comments. Should you or your staff need, please contact Jenifer Nawrocki in my Washington, D.C., office by phone at (202) 225-5961 or email at Jenifer.Nawrocki@mail.house.gov.

With much respect,

David W. Jolly
Member of Congress

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TODD ROKITA
4TH DISTRICT, INDIANA

COMMITTEE ON THE BUDGET

COMMITTEE ON HOUSE ADMINISTRATION

COMMITTEE ON EDUCATION AND THE WORKFORCE

ROKITA.HOUSE.GOV

Congress of the United States
House of Representatives
Washington, DC 20515

August 8, 2014

Dr. Margaret A. Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Dr. Hamburg:

I write today to provide comments on the Food and Drug Administration (FDA) proposed rule relating to the definition of tobacco products pursuant to the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Docket ID: FDA-2014-N-0189). This rule contemplates two options for the interpretation of the jurisdiction and authority of the FDA under the Tobacco Control Act. The first would extend the FDA's authority under the Tobacco Control Act to all products that satisfy the statutory definition of "tobacco product" under the Food, Drug, and Cosmetic Act. The second option would exempt "premium cigars" from regulation under the Tobacco Control Act.

After review of the proposed rule, I believe that the second option, with the exemption applied to premium cigars, would be the better option. Simply put, the Tobacco Control Act, when passed into law by the 111th Congress, sought to reduce the availability and targeted advertising of tobacco products to minors. In addition, Congress sought to reduce the health effects caused by habitual tobacco use. To bring premium cigars under the penumbra of regulation as a result of a law addressing those concerns would be unnecessary and improper in light of the intent of Congress. That is, premium cigars are neither targeted towards minors nor used by enthusiasts with a frequency that could reasonably be described as habitual.

It is apparent that the FDA recognizes this fact in that the exemption of premium cigars is an option within the proposed rule. That option would exempt any hand rolled tobacco that is wrapped in 100% leaf tobacco, bunched with 100% tobacco filler, weighs at least 6 pounds per 1,000 count, and is greater than $10. It is that arbitrary price qualifier that prevents the second option from being the important and effective exemption that the FDA seeks.

At $10 per cigar, the exemption would not apply to a large portion of the premium cigars available on the market today. According to Marvin Shanken, editor and publisher of the acclaimed cigar review magazine Cigar Aficionado, 416 of the 608 non-Cuban cigars rated by the publication in 2013 fall below the $10 price point. Further, the $10 qualifier does nothing to

236 CANNON HOUSE OFFICE BUILDING WASHINGTON, D.C. 20515 • (202) 225-5037 • (202) 226-0544 (FAX)

advance the goals of the Tobacco Control Act. An $8 premium cigar is no more targeted to minors nor more habitually used than an $11 premium cigar. Removing the price qualifier would still accomplish the goals sought by Congress and the FDA and would prevent unnecessary economic harm to cigar makers across the country—including National Cigar Corporation located in Frankfort, Indiana, which I represent.

I appreciate that the FDA has attempted to address the concerns of cigar enthusiasts and manufacturers across the country. However, the proposed rule has yet to adequately do so. For that reason and for those outlined above, I request that the FDA implement a rule to exempt premium cigars from regulation under the Tobacco Control Act without a price qualification. To do so would still fulfill the intent of Congress and protect the premium cigar industry and culture.

Sincerely,

Todd Rokita
Member of Congress

TER/sd

United States Senate
WASHINGTON, DC 20510

August 8, 2014

Margaret A. Hamburg
Commissioner
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Premium Cigars – Food and Drug Administration, Docket No. Docket FDA-2014-N-0189-0001

Dear Commissioner Hamburg:

We write to provide comments to FDA's Center for Tobacco Products (CTP) proposed rule to deem additional tobacco products subject to regulation under the Federal Food, Drug, and Cosmetic Act as amended by the Family Smoking Prevention and Tobacco Control Act (Docket FDA-2014-N-0189-0001).

We were pleased to see the inclusion of an "option 2" in this proposed regulation, which would exclude premium cigars from FDA regulation. And we appreciate the efforts FDA has made to understand the premium cigar industry, its products, and consumers. This industry employs between 15,000 and 20,000 American workers and is responsible for as much as $1.8 billion in annual revenue. The inclusion of "option 2" in the proposed rule is an indication FDA's recognition that premium cigars are a unique product, with a unique consumer base.

Moreover, we believe the concept of an "option 2" to exempt premium cigars is consistent with Congress' intent in the law. However, in order to properly define a premium cigar, "option 2" must be amended.

Specifically, we are unclear as to how the FDA came to the decision to impose a $10 price threshold on these products and are concerned that it will have a significant detrimental impact on these businesses. We have also heard concerns that the FDA's proposed definition could improperly exclude historic American premium cigar manufacturers that use antique machinery. Similarly, there are worries that cigars which meet all other aspects of the premium cigar definition but include uniquely adult flavorings could be excluded. Additionally, there is concern that there is no current definition of what long-leaf tobacco filler is or what predominate composition using this filler might entail, making compliance with this requirement problematic to enforce.

Thus, we have worked in a bipartisan, consensus manner to draft a definition which heeds these concerns while appropriately constraining the size of the category to ensure that only premium cigars are included. A premium cigar should be defined as any roll of tobacco that is wrapped in 100 percent leaf tobacco, bunched with 100 percent tobacco filler, contains no filter, tip or non-tobacco mouthpiece, and weighs at least 6 pounds per 1,000 count. It also must either have a 100 percent leaf tobacco binder and be hand rolled, or have a homogenized tobacco leaf binder and be made in the United States using human hands to lay the 100 percent leaf tobacco wrapper onto only one machine that bunches, wraps, and caps each individual cigar. Additionally, this should explicitly exclude cigarettes or little cigars, as defined by the FDA.

We strongly urge FDA to modify its definition of the premium cigar category to be one that can be effectively implemented and provide certainty for manufacturers, retailers and consumers. Improper definition of a premium cigar or the elimination of "option 2" would have the unintended result in the loss of American jobs, and would limit consumer freedom while unnecessarily detracting from FDA's ability to accomplish the goals Congress intended.

Sincerely,

Bill Nelson
U.S. Senator

Marco Rubio
U.S. Senator

Mary Landrieu
U.S. Senator

James Inhofe
U.S. Senator

Joe Manchin
U.S. Senator

Pat Toomey
U.S. Senator

Mazie Hirono
U.S. Senator

David Vitter
U.S. Senator

John E. Walsh

John Walsh
U.S. Senator

ROBERT P. CASEY, JR.
PENNSYLVANIA

COMMITTEES:
AGRICULTURE, NUTRITION, AND FORESTRY
FINANCE
HEALTH, EDUCATION, LABOR, AND PENSIONS
SPECIAL COMMITTEE ON AGING
JOINT ECONOMIC

United States Senate
WASHINGTON, DC 20510

August 25, 2014

The Honorable Margaret Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

I write today to share my comments on the Food and Drug Administration's (FDA's) proposed rule from the Center for Tobacco Products (CTP) to deem additional tobacco products subject to regulation under the Federal Food, Drug, and Cosmetic Act as amended by the Family Smoking Prevention and Tobacco Control Act (Docket FDA-2014-N-0189-0001).

This proposed rule provided two options for regulating cigars, and I believe that Option 2 provides the most reasonable path forward by including an exemption for premium cigars. The intent of the Family Smoking Prevention and Tobacco Control Act was to reduce the negative health impacts of smoking and prevent children and teens from accessing tobacco products. Premium cigars are expensive and labor-intensive products that are not produced for mass consumption. They are primarily sold in dedicated tobacco or cigar shops, often small businesses, which do not serve or attract minors. These products should not be included in the same category as other tobacco products such as cigarettes and chewing tobacco.

The definition in the proposed rule defines premium cigars as cigars that are wrapped in whole tobacco leaf; contains a 100 percent leaf tobacco binder; is made by manually combining the wrapper, filler, and binder; and does not have a filter, tip or non-tobacco mouthpiece, where the cap or crown of the cigar is added by hand. Additionally, these premium cigars must weigh more than six pounds per thousand.

Exempting premium cigars from tobacco regulation has bipartisan support, in recognition of the unique characteristics of these products. I urge the FDA to include Option 2 in the final rule, and I thank you for your consideration in this matter.

Sincerely,

Bob Casey, Jr.

Robert P. Casey, Jr.
United Sates Senator

ALAN GRAYSON
9TH DISTRICT, FLORIDA

COMMITTEE ON FOREIGN AFFAIRS
SUBCOMMITTEE ON WESTERN HEMISPHERE
SUBCOMMITTEE ON MIDDLE EAST AND NORTH AFRICA

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON ENERGY
SUBCOMMITTEE ON ENVIRONMENT

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September 11, 2014

Dr. Margaret Hamburg
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

On August 8, 2014, I submitted the comment that appears below to your agency.

ID: FDA-2014-N-0189-79914
Tracking Number: 1jy-8doh-amla

This is a Comment on the Food and Drug Administration (FDA) Proposed Rule: *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Extension of Comment Period*

I write in response to the Food and Drug Administrations (FDA) request for comments on proposed options for the regulation of cigars (Docket No. FDA-2014-N-0189).

I understand that the FDA taking this action to address the public health concerns associated with the use of tobacco products, but I encourage the FDA to continue to realize that not all tobacco products are created, marketed, or consumed equally. More specifically, I urge FDA to adopt a rule that reflects a modified Option 2 contained in the proposed regulation. Premium cigars should not be subject to FDA regulation. I appreciate the agencys efforts to understand the premium cigar industry, its products, and its consumers.

As you know, the premium cigar industry is responsible for employing an estimated 20,000 Americans, and realizes almost $2 billion in annual revenue. It does so through

the creation of a superior product, often using antique machinery, and sometimes utilizing uniquely adult flavorings. With those factors in mind, I urge FDA to exempt premium cigars from the proposed regulation (consistent with Congresss intent when passing the Family Smoking Prevention and Tobacco Control Act, for which I voted personally), avoid an unjustified $10 retail price threshold (a manufacturer cannot control the retail price and therefore will be unsure as to whether its products are covered, and a $10 price qualifier ignores geographic concerns, locality and excise taxes, and catalog sales), and allow for uniquely adult flavorings to be exempted from coverage.

The FDA should define a premium cigar as any roll of tobacco that is wrapped in 100 percent leaf tobacco and bunched with 100 percent tobacco filler. It should contain no filter, tip, or non-tobacco mouthpiece, and weigh at least 6 pounds per 1,000 count. Further, it should also have a 100 percent leaf tobacco binder and be hand-rolled, or have a homogenized tobacco leaf binder (traditional large cigar). Finally, a premium cigar exempted from this proposed regulation should be made in the United States, using human hands to lay the 100 percent leaf tobacco wrapper onto only one machine that bunches, wraps, and caps each individual cigar. Cigarettes and little cigars, as defined by the FDA, should be explicitly excluded in the definition.

In the opening recitals of the Family Smoking Prevention and Tobacco Control Act, Congress stated that youth access to tobacco products, and the resulting health effects of such access, represent a compelling problem that America should remedy. That alone is what the Act sought to address. That concern was never extended to premium cigars, products inherently enjoyed by adult consumers. I believe that careful review of committee consideration and floor debate of the legislation will support this view. References to this specific product are conspicuously absent from the record, and for good reason it was not Congresss intent to regulate premium cigars. Improper action by the FDA in this arena would result in the loss of thousands of American jobs, limit consumer choice, and unnecessarily detract from FDAs ability to accomplish the goals that
Congress intended.

Again, I encourage FDA to adopt a modified Option 2 that exempts premium cigars from the proposed regulation, eliminates the unjustified $10 retail price threshold, and allows for uniquely adult flavorings to be exempted from coverage. I look forward to reviewing your response to this matter, and encourage you to reach out to my Washington, D.C. office should I be able to assist you further.

I want to ensure that you and your staff are in receipt of this comment, and aware of its source given the high volume of comments received for that particular proposed rule.

If you have any questions about this matter, please do not hesitate to contact my Chief-of-Staff, Julie Tagen, at julie.tagen@mail.house.gov or (202) 225-9889.

Sincerely,

Alan Grayson

Alan Grayson
Member of Congress

LETTERS FROM FOREIGN EMBASSIES TO EXECUTIVE BRANCH OFFICIALS

January 29th, 2013

Roberta S. Jacobson
Deputy Assistant Secretary
Western Hemisphere Affairs
Department of State
Washington, D.C.

Mrs. Jacobson:

On behalf of the governments of Honduras, Nicaragua and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations to be implemented by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

The implementation of the Family Smoking Prevention and Tobacco Control Act ("Act") by the FDA is of particular concern to cigar manufacturers in Honduras, Nicaragua and the Dominican Republic since the FDA announced its intent to regulate cigars via the FDA's Center for Tobacco Products.

Regulating premium cigars as if they were cigarettes and smokeless tobacco ignores the fundamental differences between premium cigars and other tobacco products. Among other reasons why premium cigars should be afforded different regulatory treatment from cigarettes and smokeless tobacco are that premium cigars are artisan products, made from 100% tobacco and that are marketed to and enjoyed by adults. Cigars do not meet the Congressional intent of the Act, in that they are not chemically addictive, nor available to America's youth.

FDA regulation of premium cigars would harm many of the small business owners in the United States that derive their livelihoods from these prestigious products. If history is any precedent, some of the regulations that could be imposed by the agency would prove disastrous to the centuries old cigar industry that provides over 350,000 jobs among our three nations, and represents millions of dollars in export revenue. No regulatory measure should threaten such jobs, and hence raise the specter of political and economic consequences within our region. Furthermore, we are deeply concerned with the FDA's admission in their December 21, 2012 publication that these regulations are "likely to have international trade and investment effects."

As testament to our feelings on this issue, 221 members of the U.S. House of Representatives and fourteen members of the U.S. Senate have spoken in a very bi-partisan manner through the legislation that was filed, which would protect these craft products of our respective nations – The Traditional Cigar Manufacturing and Small Business Jobs Preservation Act. Many other Members of Congress have written the FDA, with our shared thoughts on this matter. This message from the House and Senate serves to echo our deep concern about the direction and intentions of the FDA.

We hope you will take our thoughts and concern into consideration as this issue is addressed.

Jorge Ramón Hernández- Alcerro
Ambassador Of Honduras

Francisco Campbell
Ambassador of Nicaragua

Aníbal de Castro
Ambassador of the Dominican Republic

January 29th, 2013

Jose Fernandez
Assistant Secretary Economic and Business Affairs
Department of State
Washington, D.C.

Mr. Fernandez:

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Jorge Ramón Hernández- Alcerro
Ambassador Of Honduras

Francisco Campbell
Ambassador of Nicaragua

Aníbal de Castro
Ambassador of the Dominican Republic

January 29th, 2013

Dr. Lawrence Deyton
Director of the FDA Center for Tobacco Products
9200 Corporate Boulevard
Rockville, MD

Dr. Deyton:

On behalf of the governments of Honduras, Nicaragua and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations to be implemented by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

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As testament to our feelings on this issue, 221 members of the U.S. House of Representatives and fourteen members of the U.S. Senate have spoken in a very bi-partisan manner through the legislation that was filed, which would protect these craft products of our respective nations – The Traditional Cigar Manufacturing and Small Business Jobs Preservation Act. Many other Members of Congress have written the FDA, with our shared thoughts on this matter. This message from the House and Senate serves to echo our deep concern about the direction and intentions of the FDA.

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Jorge Ramón Hernández- Alcerro
Ambassador Of Honduras

Francisco Campbell
Ambassador of Nicaragua

Aníbal de Castro
Ambassador of the Dominican Republic

January 29th, 2013

Dr. Margaret Hamburg
Commissioner
US Food & Drug Administration
Washington, D.C.

Dr. Hamburg:

On behalf of the governments of Honduras, Nicaragua and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations to be implemented by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

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We hope you will take our thoughts and concern into consideration as this issue is addressed.

Jorge Ramón Hernández- Alcerro
Ambassador Of Honduras

Francisco Campbell
Ambassador of Nicaragua

Aníbal de Castro
Ambassador of the Dominican Republic

January 29th, 2013

Ricardo Zúniga
Senior Director for the Western Hemisphere
National Security Council
The White House
Washington, D.C.

Dear Mr. Zúniga:

On behalf of the governments of Honduras, Nicaragua and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations to be implemented by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

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FDA regulation of premium cigars would harm many of the small business owners in the United States that derive their livelihoods from these prestigious products. If history is any precedent, some of the regulations that could be imposed by the agency would prove disastrous to the centuries old cigar industry that provides over 350,000 jobs among our three nations, and represents millions of dollars in export revenue. No regulatory measure should threaten such jobs, and hence raise the specter of political and economic consequences within our region. Furthermore, we are deeply concerned with the FDA's admission in their December 21, 2012 publication that these regulations are "likely to have international trade and investment effects."

As testament to our feelings on this issue, 221 members of the U.S. House of Representatives and fourteen members of the U.S. Senate have spoken in a very bi-partisan manner through the legislation that was filed, which would protect these craft products of our respective nations – The Traditional Cigar Manufacturing and Small Business Jobs Preservation Act. Many other Members of Congress have written the FDA, with our shared thoughts on this matter. This message from the House and Senate serves to echo our deep concern about the direction and intentions of the FDA.

We hope you will take our thoughts and concern into consideration as this issue is addressed.

Jorge Ramón Hernández- Alcerro
Ambassador Of Honduras

Francisco Campbell
Ambassador of Nicaragua

Aníbal de Castro
Ambassador of the Dominican Republic

September 25, 2015.

The Honorable
Thomas J. Vilsack
Secretary
U.S. Department of Agriculture
Washington, D.C.

Dear Secretary:

On behalf of the governments of Honduras, Nicaragua and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations being planned by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

The implementation of the Family Smoking Prevention and Tobacco Control Act ("Act") by the FDA is of particular concern to cigar manufacturers in Honduras, Nicaragua and the Dominican Republic since the FDA announced its intent to regulate cigars via the FDA's Center for Tobacco Products, and with the issuance of proposed regulations on April 25, 2014.

Based upon the Deeming Regulation document, we would encourage the Administration to pursue the "Option 2" course of action, and grant an exemption to premium cigars that meet the prescribed definition of 'premium,' though we have concerns regarding the expectation that all such cigars carry of $10 price point, as many great cigars from our region sell for less, yet meet the remaining points of the definition.

Regulating premium cigars as if they were cigarettes and smokeless tobacco ignores the fundamental differences between premium cigars and other tobacco products. Among other reasons why premium cigars should be afforded different regulatory treatment from cigarettes and smokeless tobacco are that premium cigars are artisan products, made from 100% tobacco enjoyed by adults, not children. Cigars do not meet the Congressional intent of the Act, in that they are not chemically addictive, nor available to America's youth.

Some of the regulations that are be proposed by the agency (pre-market approval, ban on samples, new user fees, etc.) would prove disastrous to the centuries old cigar industry that provide over 300,000 jobs among our three nations, and represents millions of dollars in export revenue. No regulatory measure should threaten such jobs, and hence raise the specter of political and economic consequences within our region. Furthermore, FDA regulation of premium cigars would harm many of the small business owners in the United States that derive their livelihoods from these prestigious products.

As testament to our feelings on this issue, Members of the U.S. House of Representatives and the U.S. Senate have spoken in a very bipartisan manner through legislation that was filed, which would protect these craft products of our respective nations – The Traditional Cigar Manufacturing and Small Business Jobs Preservation Act. Many other Members of Congress have written the FDA, with our shared thoughts on this matter. This message from the House and Senate serves to echo our deep concern about the direction and intentions of the FDA.

We hope you will take our thoughts and concern into consideration as this issue is addressed.

Jorge Alberto Milla Reyes
Ambassador of Honduras

Francisco Campbell
Ambassador of Nicaragua

Jose Tomás Perez
Ambassador of the Dominican Republic

September 25, 2015.

Mrs. Roberta Jacobson
Assistant Secretary of State for Western Hemisphere
U.S. Department of State
Washington, D.C.

Dear Assistant Secretary:

On behalf of the governments of Honduras, Nicaragua and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations being planned by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

The implementation of the Family Smoking Prevention and Tobacco Control Act ("Act") by the FDA is of particular concern to cigar manufacturers in Honduras, Nicaragua and the Dominican Republic since the FDA announced its intent to regulate cigars via the FDA's Center for Tobacco Products, and with the issuance of proposed regulations on April 25, 2014.

Based upon the Deeming Regulation document, we would encourage the Administration to pursue the "Option 2" course of action, and grant an exemption to premium cigars that meet the prescribed definition of 'premium,' though we have concerns regarding the expectation that all such cigars carry of $10 price point, as many great cigars from our region sell for less, yet meet the remaining points of the definition.

Regulating premium cigars as if they were cigarettes and smokeless tobacco ignores the fundamental differences between premium cigars and other tobacco products. Among other reasons why premium cigars should be afforded different regulatory treatment from cigarettes and smokeless tobacco are that premium cigars are artisan products, made from 100% tobacco enjoyed by adults, not children. Cigars do not meet the Congressional intent of the Act, in that they are not chemically addictive, nor available to America's youth.

Some of the regulations that are be proposed by the agency (pre-market approval, ban on samples, new user fees, etc.) would prove disastrous to the centuries old cigar industry that provide over 300,000 jobs among our three nations, and represents millions of dollars in export revenue. No regulatory measure should threaten such jobs, and hence raise the specter of political and economic consequences within our region. Furthermore, FDA regulation of premium cigars would harm many of the small business owners in the United States that derive their livelihoods from these prestigious products.

As testament to our feelings on this issue, Members of the U.S. House of Representatives and the U.S. Senate have spoken in a very bipartisan manner through legislation that was filed, which would protect these craft products of our respective nations – The Traditional Cigar Manufacturing and Small Business Jobs Preservation Act. Many other Members of Congress have written the FDA, with our shared thoughts on this matter. This message from the House and Senate serves to echo our deep concern about the direction and intentions of the FDA.

We hope you will take our thoughts and concern into consideration as this issue is addressed.

Jorge Alberto Milla Reyes
Ambassador of Honduras

Francisco Campbell
Ambassador of Nicaragua

Jose Tomás Perez
Ambassador of the Dominican Republic

September 25, 2015.

The Honorable
Penny Pritzker
Secretary
U.S. Department of Commerce
Washington, D.C.

Dear Secretary:

On behalf of the governments of Honduras, Nicaragua and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations being planned by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

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Jorge Alberto Milla Reyes
Ambassador of Honduras

Francisco Campbell
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Jose Tomás Perez
Ambassador of the Dominican Republic

September 25, 2015.

Mark Feierstein
Senior Director for the Western Hemisphere
at the National Security Council
The White House
Washington, D.C.

Dear Mr. Feierstein:

On behalf of the governments of Honduras, Nicaragua and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations being planned by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

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Jorge Alberto Milla Reyes
Ambassador of Honduras

Francisco Campbell
Ambassador of Nicaragua

Jose Tomás Perez
Ambassador of the Dominican Republic

September 25, 2015.

The Honorable
Maria Contreras –Sweet
Administrator
Small Business Administration
Washington, D.C.

Dear Administrator:

On behalf of the governments of Honduras, Nicaragua and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations being planned by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

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Ambassador of Honduras

Francisco Campbell
Ambassador of Nicaragua

Jose Tomás Perez
Ambassador of the Dominican Republic

September 25, 2015.

The Honorable
Jeh Johnson
Secretary
U.S. Department of Homeland and Security
Washington, D.C.

Dear Secretary:

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Ambassador of Honduras

Francisco Campbell
Ambassador of Nicaragua

Jose Tomás Perez
Ambassador of the Dominican Republic

LETTERS FROM FOREIGN EMBASSIES TO MEMBERS OF CONGRESS

September 25, 2015.

The Honorable
Bob Corker
United States Senate
Washington, D.C.

Dear Senator Corker:

On behalf of the governments of Honduras and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations being planned by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

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We hope you will take our thoughts and concern into consideration as this issue is addressed.

Jorge Alberto Milla Reyes

Ambassador of Honduras

Jose Tomás Perez

Ambassador of the Dominican Republic

September 25, 2015.

The Honorable
Bill Cassidy
United States Senate
Washington, D.C.

Dear Senator Cassidy:

On behalf of the governments of Honduras and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations being planned by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

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Jorge Alberto Milla Reyes

Ambassador of Honduras

Jose Tomás Perez

Ambassador of the Dominican Republic

September 25, 2015.

The Honorable
Ben Cardin
United States Senate
Washington, D.C.

Dear Senator Cardin:

On behalf of the governments of Honduras and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations being planned by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

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Jorge Alberto Milla Reyes

Ambassador of Honduras

Jose Tomás Perez

Ambassador of the Dominican Republic

September 25, 2015.

The Honorable
Barbara Boxer
United States Senate
Washington, D.C.

Dear Senator Boxer:

On behalf of the governments of Honduras and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations being planned by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

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Jorge Alberto Milla Reyes

Ambassador of Honduras

Jose Tomás Perez

Ambassador of the Dominican Republic

September 25, 2015.

The Honorable
Tim Kaine
United States Senate
Washington, D.C.

Dear Senator Kaine:

On behalf of the governments of Honduras and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations being planned by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

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Ambassador of Honduras

Jose Tomás Perez

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September 25, 2015.

The Honorable
Roy Blunt
United States Senate
Washington, D.C.

Dear Senator Blunt:

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Ambassador of Honduras

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September 25, 2015.

The Honorable
Ron Johnson
United States Senate
Washington, D.C.

Dear Senator Johnson:

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September 25, 2015.

The Honorable
Marco Rubio
United States Senate
Washington, D.C.

Dear Senator Rubio:

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As testament to our feelings on this issue, Members of the U.S. House of Representatives and the U.S. Senate have spoken in a very bipartisan manner through legislation that was filed, which would protect these craft products of our respective nations – The Traditional Cigar Manufacturing and Small Business Jobs Preservation Act. Many other Members of Congress have written the FDA, with our shared thoughts on this matter. This message from the House and Senate serves to echo our deep concern about the direction and intentions of the FDA.

We hope you will take our thoughts and concern into consideration as this issue is addressed.

Jorge Alberto Milla Reyes

Ambassador of Honduras

Jose Tomás Perez

Ambassador of the Dominican Republic

September 25, 2015.

The Honorable
Lamar Alexander
United States Senate
Washington, D.C.

Dear Senator Lamar:

On behalf of the governments of Honduras and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations being planned by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

The implementation of the Family Smoking Prevention and Tobacco Control Act ("Act") by the FDA is of particular concern to cigar manufacturers in Honduras and the Dominican Republic since the FDA announced its intent to regulate cigars via the FDA's Center for Tobacco Products, and with the issuance of proposed regulations on April 25, 2014.

Based upon the Deeming Regulation document, we would encourage the Administration to pursue the "Option 2" course of action, and grant an exemption to premium cigars that meet the prescribed definition of 'premium,' though we have concerns regarding the expectation that all such cigars carry of $10 price point, as many great cigars from our region sell for less, yet meet the remaining points of the definition.

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Jorge Alberto Miña Reyes

Ambassador of Honduras

Jose Tomás Perez

Ambassador of the Dominican Republic

September 25, 2015.

The Honorable
John Boozman
United States Senate
Washington, D.C.

Dear Senator Boozman:

On behalf of the governments of Honduras and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations being planned by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

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Jorge Alberto Milla Reyes

Ambassador of Honduras

Jose Tomás Perez

Ambassador of the Dominican Republic

September 25, 2015.

The Honorable
John Barrasso
United States Senate
Washington, D.C.

Dear Senator Barrasso:

On behalf of the governments of Honduras and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations being planned by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

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Jorge Alberto Milla Reyes
Ambassador of Honduras

Jose Tomás Perez
Ambassador of the Dominican Republic

September 25, 2015.

The Honorable
Brad Sherman
United States House of Representatives
Washington, D.C.

Dear Congressman:

On behalf of the governments of Honduras and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations being planned by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

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Jorge Alberto Milla Reyes

Ambassador of Honduras

Jose Tomás Perez

Ambassador of the Dominican Republic

September 25, 2015.

The Honorable
Albio Sires
United States House of Representatives
Washington, D.C.

Dear Congressman:

On behalf of the governments of Honduras and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations being planned by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

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Jorge Alberto Milla Reyes

Ambassador of Honduras

Jose Tomás Perez

Ambassador of the Dominican Republic

September 25, 2015.

The Honorable
Ileana Ros-Lehtinen
United States House of Representatives
Washington, D.C.

Dear Congresswoman:

On behalf of the governments of Honduras and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations being planned by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

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Jorge Alberto Milla Reyes

Ambassador of Honduras

Jose Tomás Perez

Ambassador of the Dominican Republic

September 25, 2015.

The Honorable
Gregory Meeks
United States House of Representatives
Washington, D.C.

Dear Congressman:

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Jorge Alberto Milla Reyes
Ambassador of Honduras

Jose Tomás Perez
Ambassador of the Dominican Republic

September 25, 2015.

The Honorable
Ed Royce
United States House of Representatives
Washington, D.C.

Dear Congressman:

On behalf of the governments of Honduras and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations being planned by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

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Jorge Alberto Milla Reyes

Ambassador of Honduras

Jose Tomás Perez

Ambassador of the Dominican Republic

September 25, 2015.

The Honorable
Christopher Smith
United States House of Representatives
Washington, D.C.

Dear Congressman:

On behalf of the governments of Honduras and the Dominican Republic, we wish to express our deep concern regarding the potential impact of regulations being planned by the U.S. Food & Drug Administration ("FDA") with respect to premium cigars, and the challenges faced by the premium cigar industry, in each of our respective countries.

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Jorge Alberto Milla Reyes

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LETTERS FROM ADMINISTRATION AGENCY REGARDING PROPOSED DEEMING RULE

June 11, 2014

VIA ELECTRONIC SUBMISSION

The Honorable Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Room 2217
Silver Spring, MD 20993
http://www.regulations.gov

Re: Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, Docket No. FDA-2014-N-0189

Dear Commissioner Hamburg:

The Office of Advocacy (Advocacy) offers the following comment to the Food and Drug Administration (FDA) in response to the above-referenced proposed rule issued on April 24, 2014.[1] The FDA issued the proposed rule to implement provisions of the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act)[2]. Since the passage of the Tobacco Control Act, small businesses that manufacture or market tobacco products have been in contact with Advocacy in anticipation of this rulemaking. After the FDA promulgated this proposal, small business owners continued to contact and meet with Advocacy to convey feedback about the proposed rule. Based on input from small business stakeholders, Advocacy is concerned that the Initial Regulatory Flexibility Analysis (IRFA) contained in the proposed rule lacks essential information required under the Regulatory Flexibility Act (RFA)[3]. Specifically, the IRFA does not discuss the quantitative or qualitative costs of the proposed rule on many potentially affected small entities. Moreover, given the extent of the anticipated costs of this proposal, the IRFA does not adequately consider or explain significant alternatives which accomplish the stated FDA objectives while minimizing the significant economic impact of the proposal on small entities. For this reason, Advocacy recommends that the FDA republish for public comment a Supplemental IRFA before proceeding with this rulemaking.

[1] 79 Fed. Reg. 23,142 (April 25, 2014). Proposed rule available at: https://www.federalregister.gov/articles/2014/04/25/2014-09491/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the.
[2] 21 U.S. Code § 387a.
[3] 5 U.S.C. § 601 et seq.

Office of Advocacy

Advocacy was established pursuant to Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within SBA, so the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The RFA, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),[4] gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, federal agencies are required by the RFA to assess the impact of the proposed rule on small business and to consider less burdensome alternatives.

The RFA requires agencies to give every appropriate consideration to comments provided by Advocacy. The agency must include, in any explanation or discussion accompanying the final rule's publication in the Federal Register, the agency's response to these written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.[5]

Background

The Tobacco Control Act authorizes the FDA to regulate the manufacture, distribution, and marketing of tobacco products to "protect public health." The Tobacco Control Act provides that other tobacco-related products can be subject to FDA regulation if the agency deems them to be regulated products under a rulemaking process referred to as the "deeming regulation."

On April 24, 2014, the FDA Center for Tobacco Products issued a proposed rule that would deem formerly unregulated or uncovered products subject to FDA regulation, including premium cigars, e-cigarettes, and hookah tobacco. In the release, the FDA proposes and requests comment on an option where it would not deem (i.e., the agency would exempt) premium cigars. The FDA is considering this option because "it has been suggested that different kinds of cigars may have the potential for varying effects on public health, based on possible differences in their effects on dual use, youth initiation and frequency of use by youth and young adults."[6]

The deeming regulations would subject newly covered products to regulatory requirements currently only applicable to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. These requirements include general controls, health warnings, and sales and marketing restrictions. Additionally, under the proposal, a previously uncovered product would be subject to FDA premarket authorization before it may be marketed in the United States if the product is "new." A tobacco product is considered "new" if it was not being marketed as of February 15, 2007 (the "Grandfather Date") or if any modification has been made to the product that was on the market before the Grandfather Date. If the FDA treats a product as "new," the product manufacturer must submit to the FDA either a Premarket Tobacco Application, a Substantial Equivalence (SE) Report, or request a Minor Modification Exemption. For purposes of an SE report, a business must cite a predicate product that was commercially marketed as of the

[4] Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. § 601 et seq.).
[5] 5 U.S.C. § 601 et seq.
[6] See proposed rule at page 8.

Grandfather Date, and contain detailed information about the cited predicate product, including complete specifications, ingredient and component information, manufacturing information, and product testing data.

In the proposal, the FDA observes that "approximately 90 percent of domestic entities affected by this rule are estimated to be small." The FDA estimates that upfront costs for small businesses will measure approximately $390,000 - $759,000 and that annual compliance costs for small businesses will measure approximately $450,000 - $541,000.[7] The FDA notes that the annual costs of the proposed rule are expected to be greater than 10 percent of sales for small manufacturers / producers. However, the FDA's Preliminary Regulatory Impact Analysis (PRIA) and IRFA[8] suggest that there is uncertainty around these cost estimates. In several portions of its analysis, the FDA concedes that it has not accurately quantified all of the costs and burdens associated with extending its authority to regulate previously uncovered products.[9]

Since the passage of the Tobacco Control Act, small businesses that manufacture or market previously uncovered products have been in contact with Advocacy in anticipation of this rulemaking. After the FDA issued the proposal, small business owners have continued to contact Advocacy to convey concerns related specifically to the proposed rule. Advocacy has heard from small businesses that market and sell tobacco products as well as previously uncovered products, small businesses in the "little cigar" industry, small businesses in the "premium cigar" industry, small businesses in the e-cigarette industry, and small businesses in the hookah industry.

The Proposed Rule's IRFA is Deficient

Because it does not adequately describe the impacts on all types of newly covered small entities and because it does not adequately explain significant alternatives that might reduce those impacts, Advocacy believes that the IRFA contained in the proposed rule is deficient, and for this reason, the FDA should republish a Supplemental IRFA for additional public comment before proceeding with this rulemaking. Under the RFA, an IRFA must contain: (1) a description of the reasons why the regulatory action is being taken; (2) the objectives and legal basis for the proposed regulation; (3) a description and estimated number of regulated small entities; (4) a description and estimate of compliance requirements, including any differential for different categories of small entities; (5) identification of duplication, overlap, and conflict with other rules and regulations; and (6) a description of significant alternatives to the rule.[10] Advocacy is concerned that because the proposed rule's IRFA is deficient, the public has not been adequately informed about the possible impact of the proposal on small entities and whether there are less burdensome significant alternatives to the proposed rule that would meet the FDA's objectives.

Given the scope of the proposal and the number of small entities that would be impacted by it, the IRFA should include more data and analysis to provide the public with sufficient information on the economic impact of the proposed rule. However, the IRFA contained in the proposed rule

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[7] See proposed rule at page 191.
[8] PRIA and IRFA available at:
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM394933.pdf.
[9] See, e.g., PRIA at pages 7, 12, 25, and 41.
[10] 5 USC § 603.

does not adequately describe and estimate the costs the proposal would impose on small entities by both omitting a substantive discussion of costs that accrue to products with many small entities and understating compliance costs. As described above, the FDA does not quantify many of the costs and burdens associated with the proposed rule in the IRFA even for product categories where the agency estimates there are a sizeable number of small manufacturers. Instead, the FDA presents data and analysis only for cigar manufacturers and uses a limited dataset that does not measure burgeoning marketplaces such as online sales.

Many small businesses have expressed concern to Advocacy regarding costs related to premarket submissions that the proposed rule would require. These small businesses have explained to Advocacy that the cost estimates in the IRFA may be understated because the FDA does not account for differences in the way that small business will comply with the proposed rule. As an example, the FDA does not recognize that the proposal may be disproportionately burdensome to small entities that do not have the legal resources of larger businesses.

Additionally, many small businesses have told Advocacy that they will have trouble utilizing the less burdensome SE premarket submission process. Because businesses in industries for newly covered products would not be able to obtain marketing orders as many of these industries, such as e-cigarettes, were not in existence as of the Grandfather Date, or they rely on proprietary technologies. Small businesses have even confided to Advocacy that the costs associated with the proposal's premarket submission requirements could force many of them to exit the market and cease operating.

Taking into account the potentially extensive costs of the proposal, the IRFA does not fully consider significant alternatives which accomplish the stated FDA objectives and which minimize the significant economic impact of the proposal on small entities. All of the alternatives currently considered in the IRFA would only make marginal changes to the overall compliance costs to small entities, such as exempting products from labeling changes. Therefore, Advocacy encourages the FDA to further consider alternatives that may be able to more greatly decrease the regulatory burden on small business while still allowing the FDA to meet its regulatory goals.

The RFA provides guidance on this issue and it instructs agencies that when faced with economic impacts as significant as those estimated by the FDA, agencies should consider alternatives such as: (1) the establishment of different compliance or reporting requirements for small entities or timetables that take into account the resources available to small entities; (2) clarification, consolidation, or simplification of compliance and reporting requirements for small entities; (3) use of performance rather than design standards; and (4) exemption for certain or all small entities from coverage of the rule, in whole or in part.[11] Advocacy believes that all of these categories of alternatives would be relevant and useful to consider as a part of this rulemaking.

Notably, the proposed rule considers some of these alternatives for one specific product category: premium cigars. In the proposal, the FDA provides detailed data showing why the agency is considering this alternative and the cost savings that exempting premium cigars would yield. While Advocacy appreciates this example of an alternative that could meet regulatory goals while significantly reducing regulatory burdens, the FDA however does not provide an analysis related

[11] See 5 U.S.C. § 603(c).

to this alternative in the IRFA for premium cigars or any other product. Advocacy is unsure of why the FDA would not consider this significant alternative in the proposal's IRFA. Further, Advocacy is concerned that the FDA did not discuss and consider other alternatives in the IRFA that would yield similar significant cost savings as exempting premium cigars would, and that the agency did not perform a similar level of analysis on the alternatives listed in the IRFA as the agency did do elsewhere in the rule related to premium cigars. Advocacy recommends that FDA extend the analysis done on premium cigars to more product types so that the FDA can ensure that it is proposing the most effective and efficient regulation possible.

Recommendations

Advocacy recommends that the FDA revise the IRFA to provide a more accurate description of the costs of the proposed rule by including a quantitative analysis of all product categories that are manufactured or marketed by small businesses. Specifically, although the FDA notes in the proposed rule that it expects the proposal to directly impact small businesses that market or manufacture cigars, pipe tobacco, hookah, and e-cigarettes, the FDA does not provide a detailed analysis of the potential impact on many of the small entities for newly covered products. As described above, the FDA provides a detailed analysis for only one alternative – not deeming premium cigars – that would yield significant cost savings for certain small businesses. Advocacy encourages the FDA to apply this analysis elsewhere in the IRFA so that not deeming other product categories can be considered and comprehensively discussed. The FDA should develop an alternative to consider regarding not deeming other "premium" products that are similarly marketed, designed, and used as premium cigars. The FDA should also provide additional data and analysis to illustrate why the benefits of deeming some of these products outweigh the substantial costs.

Advocacy also believes that even if an alternative is discussed elsewhere in the proposed rule, for purposes of the RFA analysis, it should be discussed in the IRFA portion of the proposal to allow for more substantive public comment and improved transparency around the FDA's analysis. Moreover, to improve the quality of comments received by the public and to ensure a comprehensive review under the RFA where FDA chooses to reject an alternative, the FDA should provide a policy or economic justification as to why it did not adopt each particular alternative considered.

Advocacy also recommends that the FDA should take into consideration small business stakeholders' suggested alternatives to minimize the proposed rule's potential impact. Small business representatives in contact with Advocacy observe that the FDA could still achieve its stated purposes for the premarket submission process in the deeming proposal through the use and enforcement of statutes and regulations already in effect. As an example, small business representatives note that under 21 U.S.C. § 387d(a)(1) and § 387d (c), manufacturers and importers of regulated tobacco products are required to submit (and update) specific information about the ingredients in each marketed product. Similarly, 21 U.S.C. § 387e mandates the registration of all domestic tobacco product manufacturing establishments and product listings for all regulated tobacco products manufactured at such establishments. Advocacy encourages the FDA to review and discuss statutes and regulations currently in effect as suggested by small

business stakeholders that may already achieve the purposes of the premarket submission process in the deeming proposal.

Finally, Advocacy would like the FDA to provide at least a 90-day comment period for the proposed rule given the large economic impact that it is estimated it will have on small business. Small business will need sufficient time to analyze the potential impact of this proposed rule.

Conclusion

Advocacy is concerned that the FDA's proposed rule and IRFA lack essential information needed to properly inform the agency's decision making. Specifically, the IRFA does not adequately describe the costs of the proposed rule on small entities, and the IRFA does not set forth, consider, and discuss significant alternatives which accomplish the stated FDA objectives and which minimize the significant economic impact of the proposal on small entities. For this reason, Advocacy recommends that the FDA republish for public comment a Supplemental IRFA before proceeding with this rulemaking.

By republishing a Supplemental IRFA, small businesses will have more adequate data to assess the potential impact of the proposed rule. The FDA will further gain valuable insight into the effects of the proposed rule on small business and be more transparent in explaining and justifying the choices that it made in the proposal. Advocacy also believes that the FDA should take into consideration small business representatives' suggested alternatives that may minimize the proposed rule's potential impact.

Advocacy is committed to helping the FDA comply with the RFA in the development of the proposed rule. Therefore, Advocacy stands ready to assist the FDA in the completion of a Supplemental IRFA. Advocacy looks forward to working with the FDA. If you have any questions or require additional information please contact me or Assistant Chief Counsel Dillon Taylor at (202) 401-9787 or by email at Dillon.Taylor@sba.gov.

Sincerely,

Winslow Sargeant

Winslow Sargeant, Ph.D.
Chief Counsel for Advocacy

Dillon Taylor
Assistant Chief Counsel Advocacy

Copy to: The Honorable Howard Shelanski, Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget

LETTERS FROM STAKEHOLDERS AND IMPACTED INDUSTRIES

RAN
Retail Association of Nevada

December 4, 2013

The Honorable Harry Reid
Member, United States Senate
522 Hart Senate Office Building
Washington, DC 20510

Dear Senator Reid:

On behalf of the Retail Association of Nevada (RAN), I am writing to express support for S. 772, *The Traditional Cigar Manufacturing and Small Business Jobs Act*. RAN is a statewide trade association representing more than 1,600 retail businesses in Nevada, ranging from large national chains to small independent operators. We are concerned about the potential negative impact of unintended regulations imposed upon our members that sell premium cigars.

Between April 2010 and April 2012, the US Food & Drug Administration has published seven notices in the Federal Register stating their intent to establish regulations for cigars under the Family Smoking Prevention and Tobacco Control Act (Tobacco Act). Currently, we understand that regulations may be advancing within the Administration.

We approach this issue given the significant economic impact the premium cigar industry has for Las Vegas, and Nevada as a whole. Las Vegas attracts numerous trade shows and special events associated with premium cigars. These include:

- The International Premium Cigar & Pipe Retailers Association annual convention and trade show [3,000+ attendees over five nights];
- The National Association of Tobacco Outlets annual convention and conference [2,000+ attendees over four nights];
- The Tobacco Plus Expo and conference [2,000+ attendees over four nights];
- And for 18 years, the annual Cigar Aficionado Big Smoke [5,000+ attendees over three nights.]

Regulations under consideration by the U.S. Food & Drug Administration addressing advertising and marketing could seriously threaten and jeopardize these events taking place at all, much less in Las Vegas.

The Tobacco Act, per its Congressional intent, was to address cigarettes [and smokeless products] with a focus on reducing youth consumption and use. Premium cigars are an entirely different product, and should not be regulated by the federal government. Strict regulations such as those being considered by FDA would not only threaten the aforementioned trade shows, but potentially devastate the traditional small business cigar shops of Nevada, and across the nation.

Some of the measures FDA could consider, as we believe they are, include:

- Ban on walk-in humidors, self serve cigar displays, and mail-order cigar sales;

CARSON CITY 410 South Minnesota Street • Carson City NV 89703-4272 • (775) 882-1700 Office • (775) 882-1713 Fax
LAS VEGAS 175 East Reno Avenue • Suite C-9 • Las Vegas NV 89119 • (702) 452-5448 Office • (702) 740-4381 Fax

- Ban on all flavored cigars that are enjoyed by legal-age adults;
- Deface ornate, decorative cigar boxes, often considered an art form with grotesque images, seeking to apply a cigarette standard to cigars;
- Ban on cigar events where free cigars (samples) could be available to legal-age adults;
- Limits on cigar advertising, again as an attempt to apply a cigarette standard to premium/traditional cigars;
- Imposition of new 'user fees' [tax] on cigars to finance regulations;
- Limits on special release and small-batch cigars, due to mandates that cigar blends be submitted to FDA for pre-approval before release;
- Limits on nicotine levels on cigars to near zero, severely impacting the flavor of cigars;
- Ban on marketing cigar merchandise, again as they attempt to have a cigarette standard for cigars.

These businesses only cater to adults of legal-age to purchase the products we sell. We apply a strict age verification rule, do not market to children, and do not promote products that are addictive to our customers.

For these and many more reasons, we would respectfully request your support of S. 772, *The Traditional Cigar Manufacturing and Small Business Jobs Act*, as introduced by your colleagues Senator Bill Nelson and Senator Marco Rubio. In a bipartisan spirit, Senators Bob Casey, Bob Menendez, Mary Landrieu, Joe Manchin, and Jon Tester have joined as co-sponsors with a current list of twelve Senate co-sponors. It is also significant that the entire Nevada delegation to the U.S. House of Representatives has joined the companion bill, H.R. 792, as co-sponsors, as well as your Nevada colleague Senator Dean Heller.

In the spirit of bi-partisan cooperation, these Senators have come together to help protect an industry that is not only a cornerstone within the State of Florida, but represents thousands of jobs from Miami to Las Vegas and Reno, in addition to tens of thousands of jobs in Latin America, making this a critical piece of legislation for economic and political stability in these cigar producing nations. The companion bill in the US House of Representatives (H.R. 792) now has 129 sponsors, representing members from both sides of the aisle.

The US Food & Drug Administration should be focused on protecting our nation's food supply, product safety for imports harmful to our citizens, and on approving life-saving medicines. They should not be regulating the behavior of legal-age adults, especially in the arena of products that are not addictive, without chemical additives, and do not pose a risk to the general public.

Senator Reid, your consideration and support for S. 772 would be appreciated, as it is critical to the success of the noted trade shows, tourism, and local small businesses of Las Vegas and throughout Nevada.

Sincerely,

Mary Lau

Mary Lau
President/CEO

CITY OF TAMPA

Bob Buckhorn
Mayor

January 9, 2014

Dr. Margaret A. Hamburg, Commissioner
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg,

It has come to my attention that the U.S. Food & Drug Administration - Center for Tobacco Products, is advancing regulation of cigars, as a component of its overall regulation of tobacco.

Premium cigars, it should be noted, have a historic, strong and vibrant role in the greater Tampa Bay economy, and many of the regulations that could be imposed on the industry would have a most adverse impact on these businesses within the Tampa community.

Tampa is the home for such staples of the industry, such as J.C. Newman Cigar Company, A. Fuente Cigar Company, Thompson Cigar Company, Davidoff U.S.A., Altadis U.S.A., and over seventy-five local premium cigar retail establishments, many of which are traditional family owned small businesses.

While I understand and appreciate the original intent of The Tobacco Control Act to address youth access to tobacco and chemical addiction, premium hand-made cigars do not meet this threshold. Premium cigars are enjoyed by discerning adults; are traditionally beyond the price-point for youth; are used in a celebratory or infrequent manner; and are produced in a manner that lends itself to a more artisan specialty product, than one that appeals to the general population.

I hope you take these thoughts into consideration, and recognize that as the nation's economy improves, we should be careful with regulatory actions that can adversely impact local and regional existing businesses, such as the noted premium cigar interests of Tampa.

Sincerely,

Bob Buckhorn

CONNECTICUT FARM BUREAU

775 Bloomfield Avenue, Windsor, CT 06095-2322
Phone 860-768-1100 • Fax 860-768-1108 • www.cfba.org

January 24, 2014

Senator Richard Blumenthal
90 State House Square, 10th Fl
Hartford, CT 06103

Dear Senator. Richard Blumenthal

It is our understanding that the U.S. Food & Drug Administration – Center for Tobacco Products, is advancing regulation of cigars, as a part of its overall regulation of tobacco. This is very troubling, and frankly worrisome, given that the livelihood of our businesses, our ability to provide for our families and employees, and our role in the Connecticut economy is reliant on our ability to produce and sell premium cigar quality tobacco, which some of the most sought after and prized product in the world.

We now have multiple generations of family owned cigar tobacco farms in the Connecticut River Valley. There are at least 100 family-farms, more than 5,000 seasonal workers, generating a product that has an economic value of more than $100 million, and has multiple residual economic impacts with fuel, fertilizer, machinery, and related farm needs.

Now, we learn that the FDA Center for Tobacco Products is considering new regulations that could make this challenging at best, if not impossible. For example:

- New 'user fees' on premium cigars, that drive up our costs;
- "Pre-Market Review" of cigar blends before they can go to market can jeopardize sales, and even allowing new blends to reach premium cigar retail establishments;
- Potential for production standards issued by this federal agency, and new reporting requirements that are far too overly burdensome on traditional family farms;
- There are clear relationships to international trade, with our product being shipped to Latin America for final production, and hence impact on that regional economy, as well.

They want to place limits on "self-service tobacco sales," which would cause retail shops to close their walk-in humidor that is available to their customers, and is a natural and enjoyable part of the cigar shopping experience.

Things like this, coupled with 'corporate registration' with the FDA; 'product and ingredient listing' [of our all natural tobacco?!]; and many unknown rules that we hear

are around the corner for enactment, make us wonder how our small businesses could survive, by threatening demand for our product.

We believe that the FDA should be required to conduct an economic impact analysis on any such regulations before they are allowed to enact rules that could threaten our farms. If there is legislation suitable for language such as that below (like the Farm Bill) we would ask that you advocate placement of such language.

If that is not appropriate, we believe the U.S. Food & Drug Administration (or White House Office of Management & Budget) should be required to take the following approach:

"Section _____.--Study of Impact on U.S. Tobacco Farmers and Delay of Regulation.--

"(a) Study.--
"(1) In General.--No later than 180 days from the date of enactment of this Act, the Secretary of Agriculture, acting through the office of the Chief Economist, shall submit a study of the potential economic impact, on tobacco farmers in the United States, of the federal regulation of traditional large and premium cigars under the authority of 901c of the Federal Food, Drug, and Cosmetic Act, 28 U.S.C. 387a.
"(2) Contents of Study.--
(A) In General.--The study shall assess of the potential impact of such regulation on the production of shade and broadleaf tobacco in the Connecticut River Valley and elsewhere in the United States, including an assessment of the impact on--
"(i) farm income;
"(ii) employment;
"(iii) the local economy, including sales of fertilizer, farm equipment, and fuel; and
"(iv) state and local tax revenue.
(B) Tobacco Transition Relief Program.--The study also shall assess the potential impact of such regulation on the effectiveness of the tobacco transition relief program established under section 621-624 of the American Jobs Act of 2004, 7 U.S. C. 518 et. seq.]
"(3) Submission of Study.--The study shall be submitted to--
"(A) The House Committee on Agriculture;,
"(B) the Senate Committee on Agriculture, Nutrition, and Forestry; and
"(C) the Commissioner of Food and Drugs.
"(b) No Proposed Rule Pending Study.--Until both the 180-day period described in subsection (a)(1) has ended and the study described in subsection (a) has been submitted, the Secretary of Health and Human Services may not propose a regulation on any matter that involves traditional large and premium cigars under the authority of section 901(c) of the Federal Food, Drug, and Cosmetic Act, 28 U.S.C. 387a, or any other law.

"(c) Traditional Large and Premium Cigar Defined [same as H.R. 792 /S. 772].--For purposes of this section, the term `traditional large and premium cigar'--
"(1) means any roll of tobacco that is wrapped in 100 percent leaf tobacco, bunched with 100 percent tobacco filler, contains no filter, tip or non-tobacco mouthpiece, weighs at least 6 pounds per 1,000 count, and--
"(A) has a 100 percent leaf tobacco binder and is hand rolled;

"(B) has a 100 percent leaf tobacco binder and is made using human hands to lay the leaf tobacco wrapper or binder onto only one machine that bunches, wraps, and caps each individual cigar; or
"(C) has a homogenized tobacco leaf binder and is made in the United States using human hands to lay the 100 percent leaf tobacco wrapper onto only one machine that bunches, wraps, and caps each individual cigar; and
"(2) does not include a cigarette (as such term is defined by section 900(3)) or a little cigar (as such term is defined by section 900(11)).".

Premium cigars are enjoyed by adults; are traditionally beyond the price-point for youth; are used in a celebratory manner or infrequently; and are produced with a skill that lends itself to a more artisan specialty product, than one that appeals to the general population.

We hope you take these thoughts into consideration, and work to advance H.R. 792 and S. 772, which would also address many of our concerns. Please contact us with any questions or need for additional information.

Sincerely,

Henry N. Talmage
Executive Director
Connecticut Farm Bureau Association
775 Bloomfield Ave, Windsor, CT 06095-2322
phone: 860-768-1101
fax: 860-768-1108
cell: 860-380-0767

Conn. Mass. Tobacco Growers Association

February 1, 2014

Dear Connecticut House and Senate Delegation,

It is our understanding that the U.S. Food & Drug Administration – Center for Tobacco Products, is advancing regulation of cigars, as a part of its overall regulation of tobacco. This is very troubling, and frankly worrisome, given that the livelihood of our businesses, our ability to provide for our families and employees, and our role in the Connecticut economy is reliant on our ability to produce and sell premium cigar quality tobacco, which some of the most sought after and prized product in the world.

We now have multiple generations of family owned cigar tobacco farms in the Connecticut River Valley. There are at least 100 family-farms, more than 5,000 seasonal workers, generating a product that has an economic value of more than $100 million, and has multiple residual economic impacts with fuel, fertilizer, machinery, and related farm needs.

Now, we learn that the FDA Center for Tobacco Products is considering new regulations that could make this challenging at best, if not impossible. For example:

- New 'user fees' on premium cigars, that drive up our costs;
- "Pre-Market Review" of cigar blends before they can go to market can jeopardize sales, and even allowing new blends to reach premium cigar retail establishments;
- Potential for production standards issued by this federal agency, and new reporting requirements that are far too overly burdensome on traditional family farms;
- There are clear relationships to international trade, with our product being shipped to Latin America for final production, and hence impact on that regional economy, as well.

They want to place limits on "self-service tobacco sales," which would cause retail shops to close their walk-in humidor that is available to their customers, and is a natural and enjoyable part of the cigar shopping experience.

Things like this, coupled with 'corporate registration' with the FDA; 'product and ingredient listing' [of our all natural tobacco?!]; and many unknown rules that we hear are around the corner for enactment, make us wonder how our small businesses could survive, by threatening demand for our product.

We believe that the FDA should be required to conduct an economic impact analysis on any such regulations before they are allowed to enact rules that could threaten our farms. If there is legislation suitable for language such as that below (like the Farm Bill) we would ask that you advocate placement of such language.

If that is not appropriate, we believe the U.S. Food & Drug Administration (or White House Office of Management & Budget) should be required to take the following approach:

"Section _____.--Study of Impact on U.S. Tobacco Farmers and Delay of Regulation.--

"(a) Study.--
"(1) In General.--No later than 180 days from the date of enactment of this Act, the Secretary of Agriculture, acting through the office of the Chief Economist, shall submit a study of the potential economic impact, on tobacco farmers in the United States, of the federal regulation of traditional large and premium cigars under the authority of 901c of the Federal Food, Drug, and Cosmetic Act, 28 U.S.C. 387a.
"(2) Contents of Study.--
(A) In General.--The study shall assess of the potential impact of such regulation on the production of shade and broadleaf tobacco in the Connecticut River Valley and elsewhere in the United States, including an assessment of the impact on--
"(i) farm income;
"(ii) employment;
"(iii) the local economy, including sales of fertilizer, farm equipment, and fuel; and
"(iv) state and local tax revenue.
(B) Tobacco Transition Relief Program.--The study also shall assess the potential impact of such regulation on the effectiveness of the tobacco transition relief program established under section 621-624 of the American Jobs Act of 2004, 7 U.S. C. 518 et. seq.]
"(3) Submission of Study.--The study shall be submitted to--
"(A) The House Committee on Agriculture;,
"(B) the Senate Committee on Agriculture, Nutrition, and Forestry; and
"(C) the Commissioner of Food and Drugs.
"(b) No Proposed Rule Pending Study.--Until both the 180-day period described in subsection (a)(1) has ended and the study described in subsection (a) has been submitted, the Secretary of Health and Human Services may not propose a regulation on any matter that involves traditional large and premium cigars under the authority of section 901(c) of the Federal Food, Drug, and Cosmetic Act, 28 U.S.C. 387a, or any other law.
"(c) Traditional Large and Premium Cigar Defined [same as H.R. 792 /S. 772].--For purposes of this section, the term `traditional large and premium cigar'--
"(1) means any roll of tobacco that is wrapped in 100 percent leaf tobacco, bunched with 100 percent tobacco filler, contains no filter, tip or non-tobacco mouthpiece, weighs at least 6 pounds per 1,000 count, and--
"(A) has a 100 percent leaf tobacco binder and is hand rolled;

"(B) has a 100 percent leaf tobacco binder and is made using human hands to lay the leaf tobacco wrapper or binder onto only one machine that

bunches, wraps, and caps each individual cigar; or
"(C) has a homogenized tobacco leaf binder and is made in the United States using human hands to lay the 100 percent leaf tobacco wrapper onto only one machine that bunches, wraps, and caps each individual cigar; and
"(2) does not include a cigarette (as such term is defined by section 900(3)) or a little cigar (as such term is defined by section 900(11)).".

Premium cigars are enjoyed by adults; are traditionally beyond the price-point for youth; are used in a celebratory manner or infrequently; and are produced with a skill that lends itself to a more artisan specialty product, than one that appeals to the general population.

We hope you take these thoughts into consideration, and work to advance H.R. 792 and S. 772, which would also address many of our concerns. Please contact us with any questions or need for additional information.

Sincerely,

William F. Leahey

William F. Leahey, President

YBOR CHAMBER

February 20, 2014

Dr. Margaret A. Hamburg, Commissioner
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

As we understand it, the U.S. Food & Drug Administration – Center for Tobacco Products is undertaking additional regulation of cigars as an element of its overall regulation of tobacco.

Premium cigars have played a key cultural and economic role in Ybor City since April 13, 1886. We were founded as Florida's first industrial town around the "cigar industry." Additional regulation of this fragile "home grown" business could have serious impacts on the hand-rolling cigar shops that dot our National Historic Landmark District.

As the once "cigar capital" of the world, Tampa Bay is home today to key companies in the industry including: A. Fuente Cigar Company, J.C. Newman Cigar Company, Davidoff USA, Altadis USA, Thompson Cigar Company and over 75 local premium cigar retailers.

While we appreciate the original intent of The Tobacco Control Act to address access of young people to tobacco and chemical addiction, premium cigars do not meet this threshold. Premium cigars are enjoyed primarily by adults; are usually beyond the price-point for youth; are used in a celebratory or infrequent manner; and are produced as an artisanal product that appeals to a specialized market, rather than to the general public.

I would hope that you would take the position of our Board of Directors into consideration as you more forward. Please consider the impact that further regulation could have on our local cigar bars and overall heritage tourism within Ybor City and Tampa.

Sincerely,

Thomas P. Keating

1800 E. 9th Avenue, Tampa, Florida 33605
813-248-3712 • fax 813-247-1764
www.ybor.org • email info@ybor.org

GREATER TAMPA CHAMBER OF COMMERCE

February 21, 2014

Dr. Margaret A. Hamburg
Commissioner
US Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Regulation of Premium Cigars

Dear Commissioner Hamburg,

The Greater Tampa Chamber of Commerce urges the Food and Drug Administration (FDA) to cease its impending regulation of premium cigars under the Tobacco Control Act. We believe this regulation constitutes overly-burdensome restraint on this industry.

FDA regulation of premium cigars would harm a legacy industry for the Tampa Bay area. Over seventy-five local small businesses, many of which are family owned, provide artisan cigars to customers. Some of these companies have been in business for over one hundred years. JC Newman Company, located in the historic Ybor district of Tampa, is the country's oldest family-owned premium cigar maker. Many Tampa Bay families immigrated to the United States and got their start in this county working in Ybor cigar factories. FDA regulation would endanger these companies survival and would threaten the existence of a piece of our local history.

Changes to the ways in which our local cigar companies operate, including the way they can display their products within their retail stores, alteration of the flavor of their tobacco because of new irrigation requirements, and delays, perhaps years-long, before products can be sold constitute overly-burdensome regulation. The Chamber and its 1,200 business members ask that you end attempts to regulate the premium cigar industry.

Sincerely,

Bob Rohrlack, CCE, CEcD
President and CEO

www.tampachamber.com

PO Box 420, Tampa, FL 33601 ▪ 201 North Franklin Street, Suite 201, Tampa, FL 33602-5846 ▪ 813.228.7777 ▪ (f) 813.223.7899

CAROLYN G. GOODMAN
MAYOR

May 12, 2014

Commissioner Margaret A. Hamburg, M.D.
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Re: Regulation of Premium Cigars

Dear Commissioner Hamburg:

Given the significant economic impact the premium cigar industry has not only for Las Vegas but also to the State of Nevada as a whole, please consider these comments to FDA's Center for Tobacco Products (CTP) proposed rule to deem additional tobacco products to be subject to regulation under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). (Docket FDA-2014-N-0189-0001).

Las Vegas attracts numerous trade shows, conventions and special events associated with premium cigars. These include:

- The International Premium Cigar & Pipe Retailers Association annual convention and trade show with approximately 6,000 attendees, over five nights, providing a nongaming economic impact of $7,200,000.00.
- The National Association of Tobacco Outlets annual convention and conference with an estimated attendance of 2,000, over four nights, providing a nongaming economic impact of $1,600,000.00.
- The Tobacco Plus Expo and conference lasting four nights with 4,000 attendees and a nongaming economic impact of $5,300,000.00.
- And for 18 years, the annual three-night Cigar Aficionado Big Smoke with an estimated attendance of 5,000 and estimated to have a $6,625,000.00 nongaming economic impact.

Regulations under consideration by the U.S. Food & Drug Administration addressing product sampling and path to market, i.e., pre-market review, and any projected advertising and marketing restrictions could seriously threaten and jeopardize these events taking place at all, much less in Las Vegas.

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495 S. MAIN STREET
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Strict regulations such as those being considered by FDA would not only threaten the aforementioned trade shows, but also potentially devastate the traditional small business cigar shops of Las Vegas, within the state of Nevada, and across the nation.

This is why we support H.R. 792 and S. 772, *The Traditional Cigar Manufacturing and Small Business Jobs Act*, that the entire (bi-partisan) Nevada delegation to the U.S. House of Representatives has joined as co-sponsors, as well as Nevada U.S. Senator Dean Heller. This legislation seems to be the path to protect the conventions and trade shows that call Las Vegas "home," while still appreciating the Congressional intent of the Tobacco Control Act.

We hope you take these thoughts into consideration, and recognize that as the nation's economy improves, we should be careful with regulatory actions that can adversely impact local and regional existing businesses, such as the noted premium cigar interests of Las Vegas.

Sincerely,

Carolyn G. Goodman,
Mayor, City of Las Vegas

CGG:lk

Mirage
VEGAS STARTS HERE.™

Trevor Scherrer
PRESIDENT & COO

3400 LAS VEGAS BOULEVARD SOUTH, LAS VEGAS, NEVADA 89109 P: 702.791.7117 F: 702.792.7676 mirage.com

May 12, 2014

Commissioner Margaret A. Hamburg, M.D.
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Regulation of Premium Cigars

Dear Commissioner Hamburg:

It has come to our attention that the U.S. Food & Drug Administration's Center for Tobacco Products is advancing regulations that would have an impact on premium cigars.

We approach this issue given the significant economic impact the premium cigar industry has not only for Las Vegas, but also to the State of Nevada as a whole. Las Vegas attracts numerous trade shows, conventions and special events associated with premium cigars.

Later this year, the Mirage Hotel and Casino will host the 18th annual *Cigar Aficionado* Big Smoke Weekend. This event will bring an estimated 5,000 visitors to Las Vegas over a minimum of three nights. This one event will have an estimated $6,625,000.00 nongaming economic impact on our community.

Strict regulations such as those being considered by FDA would not only threaten the aforementioned trade show, but also potentially devastate the traditional small business cigar shops of Las Vegas.

While we understand and appreciate the original intent of the Tobacco Control Act to address youth access to tobacco and chemical addiction, premium hand-made cigars do not meet this threshold. Premium cigars are enjoyed by discerning adults and are traditionally beyond the price-point for youth. For these reason, we support "Option 2" carving out premium cigars from the proposed deeming regulations.

We hope you take these thoughts into consideration, and recognize that as the nation's economy improves, we should be careful with regulatory actions that can adversely impact local and regional existing businesses, such as the noted premium cigar interests of Las Vegas.

Sincerely,

Sands
LAS VEGAS SANDS CORP.

May 12, 2014

Commissioner Margaret A. Hamburg, M.D.
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Regulation of Premium Cigars

Dear Commissioner Hamburg:

It has come to our attention that the U.S. Food & Drug Administration's Center for Tobacco Products is advancing regulations that would have an impact on premium cigars.

We approach this issue given the significant economic impact the premium cigar industry has not only for Las Vegas, but also to the State of Nevada as a whole. Las Vegas attracts numerous trade shows, conventions and special events associated with premium cigars.

Later this year, the Las Vegas Sands Expo Center will host The International Premium Cigar & Pipe Retailers Association annual convention and trade show with approximately 6,000 attendees, over five nights, providing a non-gaming economic impact of $7,200,000.00.

Strict regulations such as those being considered by FDA would not only threaten the aforementioned trade show, but also potentially devastate the traditional small business cigar shops of Las Vegas.

While we understand and appreciate the original intent of the Tobacco Control Act to address youth access to tobacco and chemical addiction, premium hand-made cigars do not meet this threshold. Premium cigars are enjoyed by discerning adults and are traditionally beyond the price-point for youth. For these reason, we support "Option 2" carving out premium cigars from the proposed deeming regulations.

We hope you take these thoughts into consideration, and recognize that as the nation's economy improves, we should be careful with regulatory actions that can adversely impact local and regional existing businesses, such as the noted premium cigar interests of Las Vegas.

Sincerely,

Andy Abboud
Senior Vice President, Government Relations
Las Vegas Sands Corp.

Sands EXPO | The Venetian | Venezia at The Venetian | Sands | Palazzo | The Palazzo

CORPORATE HEADQUARTERS
3355 LAS VEGAS BLVD. SOUTH, LAS VEGAS, NEVADA 89109
PHONE: 702.733.5728 | FAX: 702.733.5077

STEVE SISOLAK
Commissioner

Board of County Commissioners

CLARK COUNTY GOVERNMENT CENTER
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BOX 551601
LAS VEGAS NV 89155-1601
(702) 455-3500 FAX: (702) 383-6041

May 15, 2014

Commissioner Margaret A. Hamburg, M.D.
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Regulation of Premium Cigars

Dear Commissioner Hamburg:

I write to provide comments to FDA's Center for Tobacco Products (CTP) proposed rule to deem additional tobacco products to be subject to regulation under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). (Docket FDA-2014-N-0189-0001).

I approach this issue given the significant economic impact the premium cigar industry has not only for Las Vegas, but also to the State of Nevada as a whole. Las Vegas attracts numerous trade shows, conventions and special events associated with premium cigars. These include:

- The International Premium Cigar & Pipe Retailers Association annual convention and trade show with approximately 6,000 attendees, over five nights, providing a nongaming economic impact of $7,200,000.00.

- The National Association of Tobacco Outlets annual convention and conference with an estimated attendance of 2,000, over four nights, providing a nongaming economic impact of $1,600,000.00.

- The Tobacco Plus Expo and conference lasting four nights with 4,000 attendees and a nongaming economic impact of $5,300,000.00.

- And for 18 years, the annual three-night Cigar Aficionado Big Smoke with an estimated attendance of 5,000 and estimated to have a $6,625,000.00 nongaming economic impact.

Regulations under consideration by the U.S. Food & Drug Administration addressing product sampling and path to market, i.e., pre-market review, and any projected advertising and marketing restrictions could seriously threaten and jeopardize these events taking place at all, much less in Las Vegas.

Strict regulations such as those being considered by FDA would not only threaten the aforementioned trade shows, but also potentially devastate the traditional small business cigar shops of Las Vegas, within the state of Nevada, and across the nation.

This is why I support H.R. 792 and S. 772, *The Traditional Cigar Manufacturing and Small Business Jobs Act*, that the entire (bi-partisan) Nevada delegation to the U.S. House of Representatives has joined as co-sponsors, as well as Nevada U.S. Senator Dean Heller. This legislation seems to be the path to protect the conventions and trade shows that call Las Vegas "home," while still appreciating the Congressional intent of the Tobacco Control Act.

I hope you take these thoughts into consideration, and recognize that as the nation's economy improves, we should be careful with regulatory actions that can adversely impact local and regional existing businesses, such as the noted premium cigar interests of Las Vegas.

Sincerely,

Steve Sisolak
Chair

May 2014

Commissioner Margaret A. Hamburg
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

The Las Vegas Convention and Visitors Authority recently met with representatives from the Cigar Rights of America coalition regarding the potential impact on trade shows in Las Vegas as the result of the US Food & Drug Administration's current intent to establish regulations for premium tobacco products under the Family Smoking Prevention and Tobacco Control Act (Tobacco Act.)

The LVCVA approaches this issue strictly from its impact on our destination and the economic significance of the premium cigar industry for Las Vegas, and Nevada as a whole. We support the adoption of "Option 2" which would exempt premium tobacco products from the proposed regulations. Las Vegas attracts numerous trade shows and special events associated with premium cigars and such regulations would greatly affect them. These include:

- The International Premium Cigar & Pipe Retailers Association annual convention and trade show with approximately 6,000 attendees and a nongaming economic impact of $7.2 million
- The National Association of Tobacco Outlets annual convention and conference with an estimated attendance of 1,200 and a nongaming economic impact of $1.6 million
- The Tobacco Plus Expo and conference with 4,000 attendees and a nongaming economic impact of $5.3 million
- The annual Cigar Aficionado Big Smoke with an estimated attendance of 4,000 and estimated and a nongaming economic impact of $5.3 million

While these are only a few of the events in Las Vegas, they leave a significant economic footprint. These shows rely on the touch and feel of the product and such, regulations under "Option 1" addressing the advertising and marketing of these products could seriously threaten and jeopardize these events taking place in Las Vegas.

We urge you to consider "Option 2" which is supported by the premium tobacco trade show industry as well as by our Congressional delegation from Nevada. While we have also been supportive of our delegation and the bipartisan list of co-sponsors in supporting S. 772, *The Traditional Cigar Manufacturing and Small Business Jobs Act*, which seeks to provide legislative standards around this issue and exempt premium tobacco products from these regulations, we understand that adoption of "Option 2" in the current proposed regulations would most likely negate the need for this legislation.

We look forward to working with you and our trade show partners as you work to resolve these issues. The adoption of "Option 2" is extremely important to the Las Vegas economy and we welcome the opportunity to offer any important information about this issue and its impact to the noted trade shows, tourism and the Las Vegas community.

Sincerely,

Rossi Ralenkotter

LAS VEGAS CONVENTION AND VISITORS AUTHORITY
3150 PARADISE ROAD | LAS VEGAS, NV 89109 | 702.892.0711
LASVEGAS.COM | LVCVA.COM

RICK SCOTT
GOVERNOR

July 2, 2014

Commissioner Margaret Hamburg
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Hamburg:

During the early 1900's, Tampa (later to be known as "Cigar City"), boasted more than 150 cigar factories and produced more than half a billion cigars each year. Now the only remaining cigar factory in Tampa, the J.C. Newman Cigar Company, is threatened for extinction because of rules being promulgated by your agency.

From its immigrant roots to its international success, the story of the family-owned J.C. Newman is a living example of the American Dream. As Florida's oldest industry, the hand-rolling of premium cigars is a strong symbol of the rich Cuban-Latino culture and is uniquely represented by J.C. Newman.

Now, proposed FDA regulations threaten to create an undue burden on J.C. Newman and other premium cigar companies. The FDA is putting undue and excessive burdens on this family-owned company for no logical reason and forcing J.C. Newman to comply with regulations to compete with national cigarette companies that have greater resources at their disposal.

To require these companies to charge $10 for a premium cigar would unnecessarily inhibit future sales. Making matters worse, these artificial price floors only apply to small, family-owned businesses while big tobacco companies are unaffected. In addition, requiring FDA approval for each new size, shape or brand would require upwards of 5,000 hours of testing at the company's expense – a massive burden for a company like J.C. Newman, which simply does not have the financial bandwidth of national cigarette companies that have long incorporated these kinds of requirements into their bottom line.

THE CAPITOL
TALLAHASSEE, FLORIDA 32399 • (850) 488-2272 • FAX (850) 922-4292

As America's oldest family owned premium cigar maker, J.C. Newman is also one of America's historic treasures. Therefore, we are urging you to amend the proposed rule to exclude premium cigar companies like J.C. Newman from these onerous regulations. We hope that this local, family-owned business will be allowed the opportunity to compete on a fair playing field.

Sincerely,

Rick Scott
Governor

Carlos Lopez-Cantera
Lieutenant Governor

PORT TAMPA BAY

August 6, 2014

Division of Dockets Management
(HFA – 305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA-2014-N-0189, RIN 0910-AG3

Dear Commissioner Hamburg:

We have become aware that the U.S. Food and Drug Administration – Center for Tobacco Products, is advancing regulation of premium cigars as a component of its overall regulation of tobacco.

Premium cigars have a strong connection to Tampa and to our regional economy. Our community and our port have rich, historical ties to this industry dating back over 100 years. Today, over seventy-five local small businesses provide artisan cigars to customers.

While we certainly understand and appreciate the original intent of the Tobacco Control Act to address youth access to tobacco and chemical addiction, premium cigars do not meet this threshold. FDA regulation would endanger a legacy industry and would threaten the existence of a piece of local history.

We respectfully request that you refrain from regulatory actions that can adversely impact local and regional existing businesses such as the legacy cigar interests of Tampa. Thank you for your consideration.

Sincerely,

A. Paul Anderson

A. Paul Anderson,
President and CEO

1101 Channelside Drive Tampa Florida 33602-3612 P: 813.905.7678 800.741.2297 F: 813.905.5109

November 18, 2014

The Honorable Sylvia Mathews Burwell
U.S. Secretary of Health & Human Services
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Regulation of Premium Cigars

Dear Secretary Matthews-Burwell:

The Las Vegas Metro Chamber of Commerce would like to note its concern regarding the regulation of premium cigars by the Food and Drug Administration. As the largest business organization in Nevada consisting of nearly 5,000 members with approximately 230,000 employees, the Metro Chamber is supportive of the tourism and hospitality industry in the Las Vegas metropolitan region. Las Vegas' economy is based in part due to a very extensive tourism and convention industry.

Las Vegas is considered to be one of the leading international business and tourism destination cities in the world. Southern Nevada welcomes almost 40 million tourists annually and has a population of nearly two million people. In 2013, the total economic impact of tourism was $45.2 billion, supporting 47 percent of the region's gross product and 383,000 jobs, nearly half of the total workforce.

This type of regulation may have a less than desired impact on premium cigar marketing and conventions. Businesses, trade associations and civic leaders such as the Retail Association of Nevada, Mirage Hotel, the Las Vegas Convention and Visitors Authority, the Las Vegas Sands Corporation, Chairman of the Clark County, Nevada Board of County Commissioners and the Mayor of Las Vegas have expressed their concerns with the proposed regulation.

U.S. Senator Dean Heller (NV) and each member of the U.S. House of Representatives from Nevada has gone on record opposing premium cigar regulation, by serving as co-sponsors of S. 772 and H.R. 792 respectively, during the 113th session of Congress. It is also our understanding that U.S. Senate Majority Leader Harry Reid (NV) has contacted the Administration with his concerns regarding the economic impact of these regulations on the Nevada economy and the nation as a whole.

The Metro Chamber is concerned with this regulation because of the numerous trade shows, conventions, and special events associated with premium cigars held in Las Vegas on an annual basis. These events have a significant impact on the state and local economy. These events attract thousands of visitors from across the country to Las Vegas, these include, but are not limited to:

575 Symphony Park Avenue, Suite 100
Las Vegas, Nevada 89106
(702) 641-5822
www.lvchamber.com

- The International Premium Cigar & Pipe Retailers Association annual convention and trade show [3,000+ attendees/five nights];
- The National Association of Tobacco Outlets annual convention and conference [2,000+ attendees/four nights];
- The Tobacco Plus Expo and conference [2,000+ attendees/four nights];
- And for 18 years, the annual Cigar Aficionado (magazine) Big Smoke [5,000+ attendees/three nights].

Regulations under consideration by the U.S. Food & Drug Administration affecting product sampling, pre-market review, and any projected advertising and marketing restrictions would impede the ability for these events to occur.

These regulations would not only affect the aforementioned trade shows, but also have a devastating impact on traditional small business cigar shops in Las Vegas, in the State of Nevada, and across the whole nation. Local businesses and premium cigar trade shows only cater to adults of legal-age. It should be noted, that these small businesses and trade show organizers, apply a strict age verification rule and do not market to children. For these reasons, the Metro Chamber believes the wide-ranging negative economic impact must be strongly considered when reviewing these proposed regulations by the FDA.

Thank you for allowing the Metro Chamber to express its concerns regarding the regulation of premium cigar, even though the formal public comment has closed. If I can be of any assistance or provide you with any additional information, please do not hesitate to contact me.

Sincerely,

Paul J. Moradkhan

Paul J. Moradkhan
Government Affairs, Vice President

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Las Vegas, Nevada 89106
(702) 641-5822
www.lvchamber.com

City of Miami, Florida

TOMÁS P. REGALADO
MAYOR

3500 PAN AMERICAN DRIVE
MIAMI, FLORIDA 33133
(305) 250-5300
FAX (305) 854-4001

January 23, 2015

The Honorable Sylvia Mathews Burwell
Secretary, U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Secretary Mathews-Burwell:

As you are aware, the U.S. Food & Drug Administration issued a Deeming Regulation for cigars and other tobacco products on April 25, 2014. Although the Public Comment period is now closed, we feel that for the City of Miami, there are numerous issues of economic significance that should be taken into account, as this regulatory proposal is under review.

The State of Florida is the headquarters for over forty corporations in the premium cigar industry, in Tampa, Miami and Ft. Lauderdale, with Miami hosting the most corporate offices for the industry. Florida is home to at least 232 small businesses reliant upon the sale of premium cigars, with 119 in Miami with premium cigar accounts; and Miami is the base of operations for the logistics surrounding the distribution of cigars entering from Latin America, as well as raw leaf for domestic cigar production, through the Ports of Miami, Tampa and Ft. Lauderdale being utilized by the industry. Shipping, trucking, bonded storage and related operations are all based in Miami, to support the premium cigar industry.

Also specific to the Miami economy, the Little Havana community is home to numerous boutique premium cigar manufacturers. These facilities would be subject to the same federal regulations as a multinational conglomerate cigar manufacturer, and it would be impossible, for these local businesses to survive this proposed type of federal regulation.

Florida, and the greater Miami community specifically, also serves as host to dozens of premium cigar themed festivals that bring thousands of travelers to the region each year. This impact on local and state tourism should also be taken into consideration.

I believe that the proposed Deeming Regulation for premium cigars needs a comprehensive economic impact analysis addressing how such regulations could affect these facets of the Miami economy, before entering any Final Rule process, while also believing that the most serious consideration should be given to the "Option 2" path to exempting premium cigars from these proposed regulations, at all.

Please advise our office as to information that may be needed to initiate such an economic assessment, as we can facilitate an exchange with the affected business interests in the headquarters operations, distribution, retail and agricultural sectors in Miami that will be most directly impacted by any approach to regulating premium cigars.

Your attention to this matter is appreciated.

Sincerely,

Tomás Regalado
Mayor

cc: The White House Office of Management & Budget
Attention: Mr. Shaun Donovan
Office of Information & Regulatory Affairs
Attention: Mr. Howard Shelanski
725 17th Street, N.W.
Washington, D.C. 20503

The Honorable Maria Contreras-Sweet, Administrator
U.S. Small Business Administration
409 3rd Street, S.W.
Washington, D.C. 20416

Dear Administrator Contreras-Sweet:

As you are aware, the U.S. Food & Drug Administration is preparing to issue new regulations for the cigar industry, and specifically the premium cigar sector. It was reassuring to learn that the U.S. Small Business Administration issued a letter questioning the impact these regulations can and would have on the nation's small businesses, and speaking personally, upon businesses like Gurkha Cigars.

In 2011 and 2012, Gurkha Cigars (under our former Beach Cigar Group) were the beneficiaries of a combined $1.2 million in SBA financing. This enabled our company to grow, remain stable, and today we have thirty employees in the United States, through our sales, marketing, and logistics sections, and our corporate headquarters located in Tamarac, Florida. As significant, however, is the fact that our company production in Nicaragua and the Dominican Republic allows us to support 200 rollers, and an additional 600-800 seasonal and permanent employees in the agricultural and logistics stages of premium cigar production.

The types of regulations being proposed by the FDA would specifically attack a small business like Gurkha Cigars. Our company is internationally renowned for our packaging, presenting elegant and sophisticated boxes for our premium cigars, unparalleled in the industry. The FDA within the issued deeming rule stated that we, and the industry as a whole, would have to cover 30% of the package with a warning label. Of even greater concern, the new premarket approval for new blends, bans on samples, user fees and the annual compliance costs as outlined in the SBA letter to the FDA of June 11, 2014 would most certainly make it unlikely for our company to grow, and possibly survive this unprecedented new approach to cigar regulation.

Therefore, your continued advocacy on behalf of this nation's small businesses is appreciated, and we also issue our thanks for the past financial support that has facilitated much to our corporate success. However, for that success to be sustained, and replicated within the premium cigar sector, the noted regulations by the FDA must pursue the path of exemption for premium cigars. Thank you for your consideration of these remarks.

Sincerely,

Kaizad Hansotia
Owner, Gurkha Cigars

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Tamarac, FL 33321

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AMCHAMDR
AMERICAN CHAMBER OF COMMERCE OF THE DOMINICAN REPUBLIC

July 6, 2015

The Honorable Shaun Donovan, Director
White House Office of Management & Budget
725 17th Street, N.W.
Washington, D.C. 20503

Mr. Donovan:

On behalf of the American Chamber of Commerce of the Dominican Republic, we write regarding the recently issued Deeming Regulation by the U.S. Food & Drug Administration Center for Tobacco Products, as it pertains to cigars, and specifically premium cigars.

The Dominican Republic, as party to the Dominican Republic-Central American Free Trade Agreement (DRCAFTA), has a special relationship with the United States. One of DRCAFTA's explicit objectives is to strengthen the special ties of friendship and cooperation between its members, and the promotion of regional economic integration. As the leading agricultural product export to the United States, and one of the principle beneficiaries of increased exports to the United States, premium cigars are an important part of the economy in the Dominican Republic, having a significant impact on the agricultural, manufacturing, distribution and logistics sectors. The American market is the primary destination for Dominican premium cigars, making additional regulatory barriers particularly problematic, given the strong potential for adverse economic impact within the Dominican Republic. The Dominican Republic is striving to improve its economic condition, and premium cigars provide a critical source of employment, investment and trade.

Regulating premium cigars as if they were cigarettes and smokeless tobacco ignores the fundamental differences between premium cigars and other tobacco products. We are pleased that the Deeming Regulation presents the consideration of an exemption for premium cigars, and the proposed 'definition' of premium cigars seems to be consistent with industry standards, though we have concerns about the use of a $10 price as a benchmark for defining a premium cigar. We would encourage recognition that premium cigars are an artisan product, made from all natural tobacco that are marketed and sold only to adults.

According to new figures by the U.S. Department of Commerce, the Dominican Republic has experienced stable growth in cigar exports, with a recent report noting that exports have climbed from 114.7 million units in 2011 to 126.5 million units in 2014.

Within the President's Unified Regulatory Agenda, there was acknowledgement that regulating cigars would have 'international trade and investment effects.' We would encourage the FDA and the Administration to recognize not only the trade impact of regulation, but the impact such regulations could have on employment within the Dominican Republic, as well as security implications, for any approach to regulation that could threaten political stability and economic opportunity. The pre-market review and ban on premium cigar samples are cases in point that could present such issues.

This proposed cigar deeming regulation demands further economic impact analysis, and the Administration should undertake such as assessment before any regulatory measures are allowed to move forward.

We would welcome the opportunity to provide additional information, given the significance of the premium cigar industry to the Dominican Republic, and all of Latin America.

Thank you for your consideration of these concerns.

Sincerely,

Gustavo Tavares
President

cc: Amb. James Brewster, US Embassy, Santo Domingo
Howard Shelanski, Administrator, OMB/OIRA
Department of State Bureau of Western Hemisphere Affairs
Department of State Bureau of Economic and Business Affairs
National Security Council
Jodi Bond, U.S. Chamber of Commerce/Western Hemisphere

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National Cigar Corporation

National Cigar Corp.

407 NORTH MAIN STREET
P.O. BOX 97
FRANKFORT, IN 46041-0097

Dear Senator Dan Coats,

My name is James K. Pogue; I'm the President of National Cigar Corporation (a proud Indiana family owned business since 1943). Senator Coats, I wish to respectfully urge that you co-sponsor S.1461. We, as members of Indiana's cigar community and the Midwest's last remaining cigar manufacturer, are very concerned that if the Traditional Cigar Manufacturing and Small Business Jobs Preservation Act S.1461 is not passed, the Food and Drug Administration would extend its regulatory authority over premium and large traditional cigars. FDA oversight would likely impose austere advertising restrictions, costly regulatory hurdles for new types of cigars, and onerous user fees, which would fundamentally alter our natural leaf cigars as we now know them. This would include our beloved brands, such as "El Verso", "Evermore", and "Ibold", as well as the iconic, original "Marsh Wheeling Stogie", from which the term "stogie" originates.

These regulations could wipe out the entire premium cigar industry and the thousands of jobs that go with it...including cigar manufacturers like me and our 25 Indiana jobs at National Cigar Corporation, devoted employees who call Indiana home, as well as Indiana cigar retailers, cigar publications and cigar distributors. S.1461 would amend the Tobacco Control Act to prevent the FDA from issuing these additional regulations. It is by no means a renunciation of the Family Smoking Prevention and Tobacco Control Act ("Tobacco Act") of 2009, but rather a clarification of Congressional intent. The many co-sponsors of our House Bill H.R.1639 who voted for the "Tobacco Act" attest to this fact.

It is vital to note that this bill merely defines our cigar category in such a way that protects the type of cigars we manufacture, while allowing the FDA to regulate the type of products they explicitly stated warranted such when the "Tobacco Act" was passed in 2009. Please keep in mind that our products are marketed to adults only, don't have issues with youth access and usage, and lack the epidemiological concerns that warrant FDA regulation.

We currently have over 100 co-sponsors on H.R.1639 and have sponsorship in the Senate. Furthermore, we enjoy bi-partisan support by both key leadership offices as well as relevant oversight committee Members on what is a fiscally neutral, crucial bill that could save Indiana's last cigar factory. I urge you to consider co-sponsoring this crucial piece of legislation and helping to preserve a vital part of Indiana's culture and history.

On behalf of the proud Hoosier family of the National Cigar Corporation, I thank you for your support.

Sincerely,

James K. Pogue
President, National Cigar Corporation

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www.broadleafcigars.com

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National Cigar Corporation

National Cigar Corp.

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FRANKFORT, IN 46041-0097

The Honorable Joe Donnelly, Member
U.S. Senate
720 Hart Senate Office Building
Washington, D.C. 20510

July 7, 2015

Dear Senator Donnelly:

My name is James K. Pogue, and I am the last President, of the National Cigar Corporation, which up until this month was a proud Indiana business, since 1943. In 1978 this company had 128 employees, and today there are none – and I lay the loss of those jobs squarely at the feet of the federal government.

From the moment Congress enacted the unprecedented level of cigar taxation under the 'SCHIP' program, the prognosis for our business became clear, and bleak. We could not survive under these conditions. When confronted with this new tax structure, we, however, sought to keep our business and production in Indiana, as others moved operations offshore. Then, the federal government again encroached upon our business.

The very threat of federal regulation of cigars by the U.S. Food & Drug Administration was enough to realize our business could not survive, especially when coupled with the SCHIP taxes. When confronted with the prospect of pre-market approval of our blends, new user fees, testing and warning label requirements, it was simply too much for this seventy-two year old business to sustain.

You can make a statement about this, Senator Donnelly. We hope that you will co-sponsor and support S. 441, The Traditional Cigar Manufacturing and Small Business Jobs Preservation Act, as you did as a member of the U.S. House of Representatives. Perhaps if this bill was already enacted, we may still be open next month. That is simply not to be.

National Cigar Corporation was a part of this state's history and culture, serving as a symbol of small business, entrepreneurship, local ownership, and jobs that served multiple generations. Based upon our closure, we are now a symbol of how the heavy hand of the federal government can change what was once a proud heritage of service to our employees, and community.

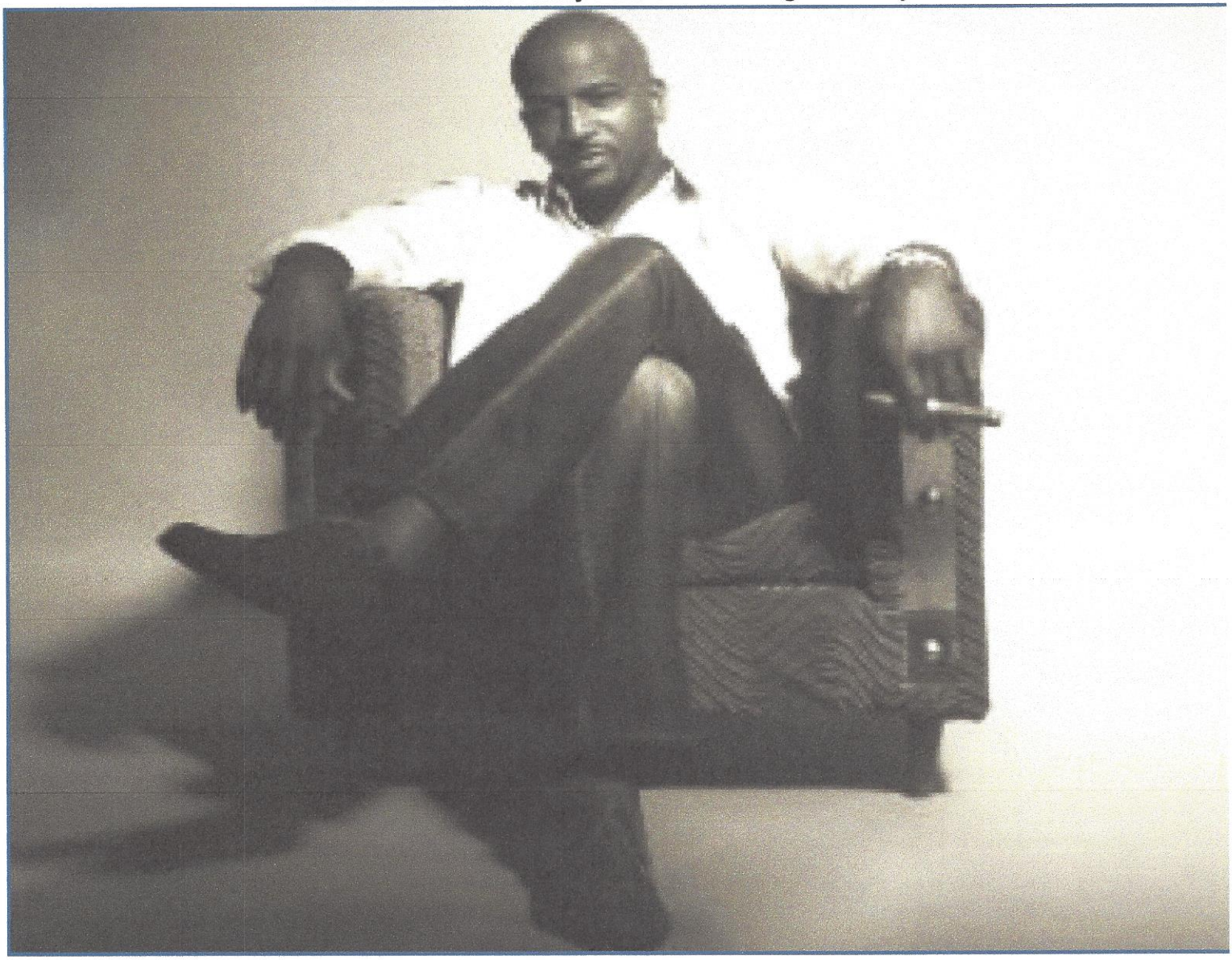
We hope you will take these words into consideration, as you consider ways in which you can support this great industry, and prevent the demise of jobs in this country, as well as internationally, through this impending threat by the U.S. Food & Drug Administration.

Sincerely,

James K. Pogue

NEWS STORIES ON MINORITY AND WOMEN OWNED PREMIUM CIGAR ENTERPRISES

Sean Williams Succesfully Breaks into the Cigar Industry



Sean Williams is one of a very few African-American brand owners in the cigar industry. In fact, his cigars have been rated as one of the top brands in the industry and received nominations and 90+ ratings from publications like *Smoke Magazine* and *Cigar Snob Magazine*. His company, El Primer Mundo (EPM) Cigars creates a distinctive portfolio of cigars with complex profiles using the best leaves from countries such as Nicaragua, Dominican Republic, Ecuador, and Brazil.

Williams has made tremendous strides in the cigar industry and within his career, but one of his biggest goals is turning EPM into an eight-figure brand. With his 10 year business anniversary approaching and a new line of cigars in the making, he's both excited and anxious to get closer to that multi-million dollar goal.

After experiencing the luxury, smoothness and relaxation of a cigar during a cruise, Williams knew he'd be involved in the cigar industry in some way. He began working with a few factories to create unique blends that offer distinctive profiles that

the average cigar enthusiasts could enjoy and afford. Ten years after that first cigar and a few trial and errors, his company, El Primer Mundo Cigars has become one of the most respected and lauded small-batch brands in the premium cigar industry. His product ratings and rankings place EPM amongst the top brands on the market.

Williams eats, sleep and literally breathes his cigar lifestyle. He understands that in order to grow his brand, he has to be cognizant of his competitors yet remain true to his product's perspective. He stays plugged to the consumers and their growing needs and even enjoys smoking cigars from other cigar makers. He believes in keeping his ear to the streets and his palate open to avoid having a single-minded approach in creating his products.

Developing a globally respected and high-ranked brand required Williams to cultivate dependable business relationships and build capital. To compete in a tight-knit industry and come out as one of the best companies meant that Williams had to make smart and tough decisions, despite the chaos and shakiness of entrepreneurship.

His sharp focus, keen business sense and an undeniably high-quality product makes Williams an entrepreneurial sensation who is making tidal waves in an industry that is skeptical of newcomers. However, he attributes his entrepreneurial success to being able to compartmentalize and stay focused. He operates by his motto that "nobody is going to believe in my dream as much as me". So, he urges anyone interested in entrepreneurship not to quit. He believes that a lot of people have great ideas, concepts, and inventions, but very few can navigate the tough times long enough to see the light at the end of the tunnel.

Williams spends most of his time traveling with brokers, giving attention to his current accounts and closing new deals. When he's not traveling, he usually ends up on his laptop or phone while smoking a cigar at a few cigar shops in Atlanta. The point: Sean Williams lives his brand. He studies it and breathes it–all to ensure that the reward of his entrepreneurial path is as luxurious, smooth and relaxing as his EPM brand.

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Cigar Aficionado: Tres Lindas Cubanas Cigars Sparking Business Success

Partners Yvonne and Yvette Rodriguez detail journey into the industry

by Richard Spiropoulos Posted: November 4, 2014

(Image: Tres Lindas Cubanas)

Whether you are a smoker or not, chances are at some point in your life you might have had cigar envy.

For some, there's just something eye-catching and inherently trendy about firing up a stogie.

When it comes to cigars, it's no secret that Cubans are top of the line, but of course ever since the 1962 embargo, everything with a "Made in Cuba" sticker became illegal here. But there's another coveted option: Nicaraguans.

They come highly recommended by true cigar aficionados and are arguably just as good. Other countries like the Dominican Republic and Honduras make their own cigars, but since Cuba was the first officially recognized nation to cultivate, they've become the gold standard to which all others are judged.

Tres Lindas Cubanas Cigars, a black-owned cigar line is carving out a name for itself in the industry. **BlackEnterprise.com** caught up with twins **Yvonne and Yvette Rodriguez**, two of the four partners in the company, to talk about how they got into the industry and the family legacy that led them to a lucrative enterprise.

They recall memories of growing up on South Florida, where their grandmother would smoke cigars. The partners began working on starting the business last year after a trip out to Costa Rica.

"We were sitting by the pool and we met a gentleman who owns a cigar factory in Nicaragua. We frequent cigar shops on the regular and we partnered up to receive cigars from him regularly and before we knew it we were hashing out blends," the sisters recall.

Tobacco flavor comes off the soil and climate of a location before it is harvested. By January they had a team in place here and in Nicaragua to grow, blend and roll the leaves and since then they haven't looked back.

They created and market their cigar line in the spirit and reflection of today's cigar aficionado; Urban sophistication and yet traditional.

Check out more on how the business began on the next page ...

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(http://mediad.publicbroadcasting.net/p/wlrn/files/styles/x_large/public/201503/YvetteandYvonne.j

Twin sisters, Yvonne Rodriguez,left, and Yvette Rodriguez, right, explore race in Cuban Culture with their cigar line Tres Lindas Cubanas Cigars.

CREDIT NADEGE GREEN / WLRN

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Hear Yvonne and Yvette Rodriguez talk about their personal experiences as Afro-Cuban women and how that inspired their cigar company "Tres Lindas Cubanas Cigar."

Yvette Rodriguez is enjoying one of her cigars with a glass of bourbon inside Brickell Cigar Co. just on the edge of Miami's Little Havana neighborhood where she grew up.

Brickell Cigar was the first store to carry the boutique cigar line she started with her twin sister, Yvonne, two years ago, Tres Lindas Cubanas Cigars.

Yvette runs down the names of the company's three signature smokes.

"La Negrita, La Mulata and our Clarita," she says pointing to the boxes along a brick-red wall.

The names loosely translate to: Dark-skinned, tan complexion and fair-skinned.

For Yvonne and Yvette, their cigar line is more than just a business venture; it's an unexpected way to talk about race in Cuban culture and their experience being black and Cuban.

Both of Yvonne and Yvette's parents were born in Cuba where the Afro-Cuban population is large. But the sisters were born and raised in Miami in a predominantly white Cuban community.

"It was hard for us to define what we were," says Yvonne, exhaling a cloud of smoke from a Tres Lindas Cubanas (http://treslindascubanascigars.tumblr.com) cigar.

At school, she says most of her friends thought all Cubans were white. When they looked at her and Yvette with their dark brown skin and curly hair, they were confused.

They assumed one of the twins' parents must have been African-American.

"There aren't that many Afro-Cuban exiles that came to Miami back in the day, so then it's best we informed them," says Yvonne between sips of bourbon. "There's not a half and half. We are black Cubans, you know."

Yvette Rodriguez adds even Cubans in Miami are sometimes confused.

"They know there are Spanish-speaking black Cubans that exist," she says. But they're still surprised when they meet Yvette and Yvonne.

"I'll be like, 'Buenos dias,'" says Yvette. "And it's like, 'Oh, habla español?'"

(http://mediad.publicbroadcasting.net/p/wlrn/files/styles/x_large/public/201503/Screen_Shot_2015-03-03_at_11.55.17_AM.png)

Tres Lindas Cubanas Cigars

CREDIT TRES LINDAS CUBANAS CIGARS

The sister says instead of getting frustrated by the almost daily public reaction to them — unapologetic Spanish-speaking black women — they decided to celebrate the stereotypes of race in Cuban culture through something very Cuban: cigars.

Their cigar-puffing Cuban grandmother, Esperanza Gonzalez, or Wezee as the twins called her, helped inspire Tres Lindas Cubanas Cigars.

"She loved smoking cigars," Yvette says, "My mom hated it."

Gonzalez smoked her way from from Havana, Cuba to Little Havana in 1969. She was very fair skinned; people thought she was white.

Her complexion inspired the twins' lighter "la Clarita" cigar. But Yvonne and Yvette had much darker skin — that's the "la Negrita" cigar.

The sisters say even though Gonzalez didn't look obviously black, she identified as a black woman, and taught her twin granddaughters to embrace what they looked like.

“She would always say, ‘Us black women we have to do this, this and that,’” says Yvette. “It was very confusing to a 5-year-old to be saying, ‘We black women,’ and she was white... It was a very good lesson.”

The third cigar name, “la Mulata,” represents all the shades in between the twins and their grandma.

Yvonne says when people talk about skin color; they tend to highlight negative stereotypes.

She says there can be negative connotations to being called “dark-skinned,” but when she and her sister use “la Negrita” for their cigar, they’re celebrating the positive aspects of being dark-skinned.

“When you think of a strong black woman, she’s a leader. She’s the strongest. That’s why our maduro blend is the strongest,” Yvonne says.

But Yvonne and Yvette didn’t want their brand to *just* reflect their race.

They also wanted a way to proclaim their Cuban heritage.

So while the cigar names tackle racial stereotypes, their company name — Tres Lindas Cubanas Cigars —pays homage to Cuba and an old Cuban song by the same title.

"It’s like a Cuban anthem,” says Yvette. “When the song comes on the Cuban woman gets up."

Hear Tres Lindas Cubanas below: