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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