

Presentation to the Office of Management and Budget

May 4, 2021

Meeting Agenda

- 1. Introductions
- 2. About our 126-year-old family business
- 3. How we roll premium cigars in Tampa
- 4. FDA research on premium cigars
- 5. Concerns with the draft Final Rule
- 6. Suggestions for improvement
- 7. Questions and answers
- 8. Thank you!

2. About our 126-year-old family business

- J.C. Newman came to America from Austria-Hungary in 1888.
- When he founded our company in the family barn in <u>1895</u>, J.C. was one of 42,000 American cigar manufacturers.
- 125 years later, we are the <u>only one</u> of those 42,000 American companies still owned and operated by the founding family.
- We are a small, four-generation, family-owned and -run business.



- Our Tampa, Florida factory was built in 1910. It's called "<u>El Reloj</u>" and is in the <u>Ybor City Historic District</u>.
- Of the 150 cigar factories in Tampa, we are the <u>last one still operating</u>.
- We have <u>145 employees</u>, many of whom have worked here for decades.
- We roll premium cigars both by hand and by <u>hand-operated</u>, <u>antique</u> <u>cigar machines from the 1930s</u>.



- Our <u>antique cigar machines</u> were built in the 1930s and have more than <u>10,000 moving parts</u>.
- Unlike high-speed mass-market cigar machines, the wrapper tobacco leaf for each cigar is applied <u>by hand</u>.
- A slow and labor-intensive process.
- We use the <u>same quality</u>, <u>aged</u>
 <u>cigar tobacco</u> as handmade cigars.
- The definition of "premium cigar" in the draft Final Rule would exclude these cigars rolled in our factory.









J.C. Newman Cigar Co. America's Oldest Family-Owned Premium Cigar Maker

AMERICAN Hand-operated, antique cigar machine cigars

- El Reloj
- Factory Throwouts





IMPORTED Handmade cigars

- Brick House
- Quorum







4. FDA Research on Premium Cigars

- Research conducted and/or funded by FDA has found that:
 - 1. Children do not smoke premium cigars.

 Karin A Kasza et al., Tobacco Product Use by Adults and Youths in the United States in 2013 and 2014, 376 New England Journal of Medicine 342–353, at Supp. Appx. Table S4 (Jan. 26, 2017).
 - 2. Premium cigars are smoked infrequently.

 Catherine G. Corey et al., Little Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults United States, 2012–2013, MORBIDITY AND MORTALITY WEEKLY REPORT (Aug. 1, 2014).
 - 3. Premium cigars are distinct from other tobacco products.

 Catherine G. Corey et al., US Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings From the Population Assessment of Tobacco and Health (PATH) Study, 2013–2014, NICOTINE & TOBACCO RESEARCH, at 7 (SEP. 15, 2017).
 - 4. Smoking premium cigars does not increase the risk of mortality for the 97% of consumers who smoke fewer than 1 premium cigar per day.

 Carol H. Christensen et al., Association of Cigarette, Cigar, and Pipe Use With Mortality Risk in the US Population, JAMA INTERNAL MEDICINE (FEB. 19, 2018), AT E6 (TABLE 3).
- The definition of "premium cigars" in these studies includes the cigars that we roll in Tampa using hand-operated antique cigar machines from the 1930s.
- As a science-based agency, FDA should define "premium cigar" as the research has done.

5. Concerns with the draft Final Rule

- 1. It requires HPHC testing (pages 121 and 200)
 - In January 2021, FDA wrote: "FDA recognizes that we have not provided a list of harmful and potentially harmful constituents (HPHCs) specific for cigars or analytical methods to measure the HPHCs."
 - Testing premium cigars has proved unreliable (see attached article).
 - FDA has indefinitely delayed standalone HPHC testing (see attached).
 - It is expensive, particularly for low-volume products.
- 2. It requires stability testing (page 85)
 - It is expensive and would be of little value to the agency.
- 3. It requires complex environmental assessments (page 79) (see attached).
- 4. It does not provide a streamlined SE process for premium cigars.
- 5. It adopts Judge Mehta's definition of "premium cigar" (page 181) that would exclude J.C. Newman's historic Tampa cigar factory.

6. Suggestions for improvement

- 1. Please do not require HPHC testing for premium cigars until FDA adopts a list of HPHCs and analytical testing methods for cigars.
- 2. Please do not require stability testing for premium cigars.
- 3. Please give a categorical exemption to EAs for premium cigars as FDA did for provisional SE products first sold between 2007 and 2011.
- 4. Please adopt a streamlined SE process for premium cigars.
- 5. Please define "premium cigar" as the studies have done. FDA can do this by adopting the legislative definition of "premium cigar" in S. 438 or the one passed by the House of Representatives last year in H.R. 2339 (excluding the unenforceable price element). Both include J.C. Newman's historic Tampa cigar factory just like the definitions used in the studies cited on page 9.

6. Suggestions for improvement

<u>Definition of "Premium Cigar" in S. 438</u>

"(C) TRADITIONAL LARGE AND PREMIUM CIGAR DEFINED.—For purposes of this paragraph, the term 'traditional large and premium cigar'—

"(i) 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—

"(I) has a 100-percent leaf tobacco binder and is hand rolled;

"(II) 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

"(III) 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

"(ii) 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)).".

The bold and underlined text includes J.C. Newman's historic Tampa cigar factory.

6. Suggestions for improvement

Definition of "Premium Cigar" in H.R. 2339

- "(I) is wrapped in whole tobacco leaf;
- "(II) contains a 100-percent leaf tobacco binder;
- "(III) contains primarily long filler tobacco;
- "(IV) does not have a characterizing flavor other than tobacco;
- "(V) weighs more than 6 pounds per 1000 units;
- "(VI) has no filter, tip, or non-tobacco mouthpiece;
- "(VII) (aa) is made by combining manually the wrapper, filler, and binder and is capped by hand; or

 "(bb) has a homogenized tobacco leaf binder and is made in the United States using human hands to lay
 the 100-percent leaf tobacco binder onto only one machine that bunches, wraps, and caps each
 individual cigar; and
- "(VIII) has a retail price (after discounts or coupons) per eigar of no less than
 - "(aa) for calendar years 2019 and 2020, \$12; and
 - "(bb) for each subsequent calendar year, \$12 multiplied by any percent increase in the Consumer Price Index for all urban consumers (all items; U.S. city average) since calendar year 2020."; and"

The bold and underlined text includes J.C. Newman's historic Tampa cigar factory.

Any price element is unenforceable and would be struck down. Here's why: Retailers set their own retail prices, which vary widely due to large differences in state taxes. For example, one of our premium cigars that sells for \$7 in Florida sells for \$11 in California and \$15 in a Las Vegas casino. A cigar could be above a threshold in one state but not another, especially if a retailer decides to discount a product in a close-out sale. Manufacturers would not know if their product was below the threshold and if they needed to comply with FDA regulation. A minimum wholesale price is no better and FDA lacks the authority to set minimum prices, particularly in intra-state sales where the vast majority cigars are sold.

7. Questions and answers



J.C. Newman Cigar Co. America's Oldest Family-Owned Premium Cigar Maker

8. Thank you!

J.C. Newman Cigar Company in 1905:



J.C. Newman Cigar Co. America's Oldest Family-Owned Premium Cigar Maker

8. Thank you!

And 100 Years Later:

