The Regulation of Premium Cigars

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Disclosures

Since leaving Federal Service in 2017, I have received funds for work done

- as a research professor at Georgia State University (ongoing)
- as an independent contractor for CDC through McKing Consulting and Cherokee National Operational Systems (ongoing)
- for the World Health Organization Tobacco Free Initiative (ongoing)
- on the Scientific Advisory Boards of several academic tobacco research projects (ongoing)
- as a consultant for Pfizer (ended in 2019)
- as a Special Government Employee of the U.S. Food and Drug Administration (ended in 2018)

Three Questions

- Why are there questions about premium cigars?
- How are premium cigars defined?
- How does scientific research inform FDA tobacco regulation?

Proposed Deeming Rule (NPRM)

April 25, 2014

FDA proposed 2 options

Option 1, all products meeting the definition of a ‘‘tobacco product,’’ except accessories of newly deemed tobacco products, would be deemed.

Option 2 was the same as Option 1, except a subset of cigars known as ‘‘premium cigars’’ would be excluded.

https://www.federalregister.gov/documents/2014/04/25/2014-09491/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the

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Deeming Regulation

May 10, 2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA–2014–N–0189]

RIN 0910–AG38

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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 877–287–1373, *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule

https://www.gpo.gov/fdsys/pkg/FR-2016-05-10/pdf/2016-10685.pdf

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Final Deeming Rule

May 10, 2016

"FDA has concluded that:
(1) All cigars pose serious negative health risks,
(2) the available evidence does not provide a basis for FDA to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion, and
(3) premium cigars are used by youth and young adults. The fact that some premium cigar smokers might smoke such products infrequently or report that they do not inhale does not negate the adverse health effects of tobacco smoke or demonstrate that cigars do not cause secondhand smoke-related disease in others. Therefore, we find there is no appropriate public health justification to exclude premium cigars from the scope of the final deeming rule and that it is appropriate to deem them."

https://www.gpo.gov/fdsys/pkg/FR-2016-05-10/pdf/2016-10685.pdf

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Cigar Association of America Versus FDA

August 19, 2020

"In issuing the Final Deeming Rule, the FDA arbitrarily failed to address commenters' requests for a streamlined substantial equivalence process for premium cigars undergoing premarket review. Accordingly, the court remands the Final Deeming Rule for the limited purpose of considering that issue anew and enjoins enforcement of the premarket review requirements against premium cigars during that time. In all other respects, however, Defendants' actions were lawful, reasonable, and adequately explained."

"Accordingly, the court remands the Final Deeming Rule for the limited purpose of considering whether a streamlined substantial equivalence process is appropriate for premium cigars."

https://mcusercontent.com/57bb6c487fe271ada7d283d9b/files/61da87e2-3450-4c1a-b9cb-496f18d4dfcc/August_19_2020_District_Court_Opinion_on_SE_and_Premium_Cigars.pdf

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Premium cigars – NPRM definition

April 25, 2014

FDA would propose to define a covered cigar to mean: any cigar as defined in this part, except a cigar that:

(1) Is wrapped in whole tobacco leaf;
(2) contains a 100 percent leaf tobacco binder;
(3) contains primarily long filler tobacco;
(4) is made by combining manually the wrapper, filler, and binder;
(5) has no filter, tip, or non-tobacco mouthpiece and is capped by hand;
(6) has a retail price (after any discounts or coupons) of no less than $10 per cigar (adjusted, as necessary, every 2 years, effective July 1st, to account for any increases in the price of tobacco products since the last price adjustment);
(7) does not have a characterizing flavor other than tobacco; and
(8) weighs more than 6 pounds per 1000 units.

https://www.federalregister.gov/documents/2014/04/25/2014-09491/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the

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ANPRM – Regulation of Premium Cigars

March 26, 2018

Explain what you believe to be the particular defining characteristics of premium cigars. These characteristics could include, but not be limited to:

a. Size (*e.g.,* length, ring gauge, total weight).
b. Tobacco filler type and minimum required percentages of each filler per cigar.
c. Fermentation type.
d. Wrapper and binder composition (*e.g.,* whole leaf, reconstituted or homogenized tobacco leaf).
e. Where the tobacco used for premium cigar filler or wrappers is grown, and whether differences in growing practices for that tobacco, as compared to tobacco used in other cigars, result in different health impacts.
f. Presence or absence of a filter.
g. Presence or absence of a mouthpiece.
h. Manufacturing and assembly process (*e.g.,* including any production by hand or by machine).
i. Rate of production (*e.g.,* "produced at no more than [insert number] units per minute").
j. Presence or absence of flavor imparting compounds, flavor additives, or characterizing flavors other than tobacco.
k. Presence or absence of any additives other than cigar glue.
l. Nicotine content.
m. Tar delivery amounts (and how this should be defined and measured).
n. Carbon monoxide delivery amounts (and how this should be defined and measured).
o. Retail price.
p. Frequency with which price changes are initiated by particular levels in the distribution chain (retailers, manufacturers, importers, and/or distributors).
q. Packaging quantity and size.

https://www.regulations.gov/docket/FDA-2017-N-6107

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Premium cigars - definition

August 19, 2020

The FDA provided an updated definition of a premium. A cigar that:

(1) is wrapped in whole tobacco leaf;
(2) contains a 100 percent leaf tobacco binder;
(3) contains at least 50 percent (of the filler by weight) long filler tobacco (i.e., whole tobacco leaves that run the length of the cigar);
(4) is handmade or hand rolled (i.e., no machinery was used apart from simple tools, such as scissors to cut the tobacco prior to rolling);
(5) has no filter, nontobacco tip, or nontobacco mouthpiece;
(6) does not have a characterizing flavor other than tobacco;
(7) contains only tobacco, water, and vegetable gum with no other ingredients or additives; and
(8) weighs more than 6 pounds per 1,000 units."

https://mcusercontent.com/57bb6c487fe271ada7d283d9b/files/61da87e2-3450-4c1a-b9cb-496f18d4dfcc/August_19_2020_District_Court_Opinion_on_SE_and_Premium_Cigars.pdf

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PREMARKET REVIEW

Product Review

- Includes
  - Investigational tobacco products (ITP)
  - New product review (PMTA)
  - Substantial equivalence (SE)
  - Exemption from SE (SE EX)
  - Modified risk tobacco products (MRTP)

- Applicant must provide adequate evidence for FDA to make a finding – the evidentiary burden is on the applicant
- FDA uses scientific research to evaluate the evidence provided by the applicant

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The Population Health Standard

- Appropriate for the protection of public health, considering:
  - The risks and benefits to the population as a whole
  - The increased or decreased likelihood that existing users of tobacco products will stop using such products
  - The increased or decreased likelihood that those who do not use tobacco products will start using such products
- Not the same as safety and efficacy

Product Review – Statutory Questions

- PMTA - Is the marketing of a new product appropriate for the protection of public health?
- SE - Do differences between a new product and a predicate product raise different questions of public health?
- MRTP - Will the product as it is actually used by consumers significantly reduce the harm and risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole?

Population Health Factors that go into product authorization decisions

1. the relative risk to smokers of combusted products versus users of the new product
2. the likelihood that current smokers of combusted products will switch completely to the new product
3. the likelihood that the product will decrease complete cessation of smoking
4. the relative risk to poly users
5. the likelihood of poly use
6. the relative risk of use of the new product compared to non use of tobacco products
7. the likelihood that adult non-users will initiate use of the product
8. the likelihood that adult non-users who initiate use of the product will transition to more harmful combusted products
9. the risk to health of youth and adolescents initiating the new product including adolescent development
10. the likelihood that youth and adolescents will initiate use of the new product
11. the likelihood that youth and adolescents who initiate use of the product will transition to more harmful combusted products

PRODUCT STANDARDS

Product Standards

Through rulemaking, the Tobacco Control Act allows adoption of "…tobacco product standards… appropriate for the protection of public health." Sec 907.

- Nicotine yields
- Reduction or elimination of constituents, including smoke constituents
- Construction, components, ingredients, additives, constituents, and properties of the tobacco product
- Provisions for testing or measuring product characteristics
- Restrictions on sale and distribution
- Form and content of labeling for the proper use of the tobacco product

The evidentiary burden for product standards rests on FDA

https://www.gpo.gov/fdsys/pkg/BILLS-111hr1256enr/pdf/BILLS-111hr1256enr.pdf

Product Standards

Product standards cannot do the following:

"(3) LIMITATION ON POWER GRANTED TO THE FOOD AND DRUG ADMINISTRATION.—Because of the importance of a decision of the Secretary to issue a regulation—

"(A) banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products; or

"(B) requiring the reduction of nicotine yields of a tobacco product to zero,

the Secretary is prohibited from taking such actions under this Act.

https://www.gpo.gov/fdsys/pkg/BILLS-111hr1256enr/pdf/BILLS-111hr1256enr.pdf

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Product Standards – Decision Points

FDA needs to have a legally defensible rationale and be able to enforce the standard (Does a specific marketed product meet the standard?)

- To determine whether a standard is appropriate, FDA needs to answer these questions. Is the standard
  - Justifiable – is there adequate evidence?
  - Necessary – is this the least costly alternative to achieve the goal?
  - Appropriate – will it do what it claims to do?
  - Unambiguous – is the requirement clear?
  - Measurable – are there methods to measure?
  - Quantifiable – can the methods distinguish products that meet the standard from products that do not?

Product Regulation and Review Scientific Considerations

Information
- Materials
- Ingredients
- Design
- Composition
- Constituents
- Other features
- Marketing

Impact
- Appeal
- Addictiveness
- Use Behavior
- Exposure
- Pharmacokinetics
- Toxicity
- Perception
- Initiation
- Cessation

Public health
- Morbidity
- Mortality

Questions?

Product Standard Evidence

- Evidence for an adverse impact on population health
- Evidence of causality or association of the item proposed to be regulated with the adverse impact
- Evidence that the proposed (quantitative) requirement would end or ameliorate the adverse impact
- Viability of technical means of meeting the requirement
- Quantitative estimate of the public health benefit
- Costs associated with meeting the requirement
- Prediction of quantitative impact of other related changes that may limit the benefit of the requirement
- Alternative ways which were considered to address the adverse impact along with estimated benefit and cost
- Possible unintended/secondary consequences of the requirement, their costs, and benefits