



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA-2017-N-6107]

RIN 0910-AH88

Regulation of Premium Cigars

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to obtain information related to the regulation of premium cigars under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), and regulations regarding the sale and distribution of tobacco products. Specifically, this ANPRM is seeking comments, data, research results, or other information that may inform regulatory actions FDA might take with respect to premium cigars.

DATES: Submit either electronic or written comments by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 90 DAYS AFTER DATE OF

PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2017-N-6107 for “Regulation of Premium Cigars.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469,

September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nathan Mease or Deirdre Jurand, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 1-877-287-1373, AskCTP@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On July 28, 2017, FDA announced a new comprehensive plan for tobacco and nicotine regulation that will serve as a multi-year roadmap to better protect children and significantly reduce tobacco-related disease and death. As part of that announcement, FDA stated that it would solicit additional comments and scientific data related to the patterns of use and resulting public health impacts from premium cigars and consider the appropriate regulatory status of premium cigars. The goal is to ensure that FDA has a broad scientific and regulatory foundation to efficiently and effectively implement the Tobacco Control Act. Moreover, the regulatory considerations with respect to premium cigars, their use, and related public health issues continue to be of significant interest to some stakeholders, as well as a topic of ongoing and emerging research. Given the ongoing interest from many parties and sectors, such as industry and Members of Congress, in the regulatory status of premium cigars, FDA is issuing this

ANPRM to request relevant new and different information, data, and analysis not submitted in response to FDA's proposed deeming rule (79 FR 23142, discussed below) that could inform FDA's regulation of premium cigars.

The Tobacco Control Act was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate tobacco products (Pub. L. 111-31). Specifically, section 101(b) of the Tobacco Control Act amends the FD&C Act by adding a new chapter that provides FDA with authority over tobacco products. Section 901 of the FD&C Act (21 U.S.C. 387a), as amended by the Tobacco Control Act, states that the new chapter in the FD&C Act (chapter IX--Tobacco Products) (21 U.S.C. 387 through 387u)¹ applies to all cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Secretary of Health and Human Services by regulation deems to be subject to the chapter.

In the *Federal Register* of April 25, 2014 (79 FR 23142), FDA published a proposed rule seeking to deem additional products meeting the statutory definition of "tobacco product" in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), except accessories to those products, to be subject to chapter IX of the FD&C Act (the proposed deeming rule). In that proposed rule, FDA proposed two, alternative, options: Option 1 proposed to extend the Agency's tobacco product authorities to all products that meet the definition of "tobacco product" in the FD&C Act, except accessories of newly deemed tobacco products, while Option 2 proposed to extend the Agency's tobacco product authorities to all tobacco products set forth in Option 1, except so-called premium cigars (79 FR 23142 at 23150 through 23152). After carefully considering the public comments on the rule, the Agency decided to adopt Option 1, concluding that there was no appropriate public health justification to exclude premium cigars from regulation. Specifically,

¹ In the U.S. Code, the tobacco control provisions constitute a new Subchapter IX of Chapter 9, which constitutes the Federal Food, Drug, and Cosmetic Act.

FDA 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. FDA noted that, although some premium cigar smokers might smoke these products infrequently or report that they do not inhale, these behaviors do not negate the adverse health effects of tobacco smoke or demonstrate that cigars do not cause secondhand smoke-related disease in others. Consequently, premium cigars were included in the scope of the final deeming rule published on May 10, 2016 (81 FR 28974 at 29020) to more effectively protect the public health.

We received numerous comments on the deeming proposed rule with respect to premium cigars, both in favor of and against regulating these products. However, the comments against regulation provided little data to support the opinions expressed and, where studies were submitted, provided little information about the studies cited.

FDA is seeking comments, evidence, information, data, and analysis that were not submitted in response to the proposed deeming rule, or that may have become available since then, that could further inform FDA's thinking about the regulation of premium cigars. One example of the type of information that would be responsive to this request is a recent publication that assessed use patterns and related behaviors of smokers of "premium" and other cigar types (Ref. 1). This paper, the PATH Study Paper, analyzed findings from the 2013-2014 Population Assessment of Tobacco and Health (PATH) Study with a focus on smokers of filtered cigars, cigarillos, and traditional cigars, which were further classified by study authors as either

“premium” or “non-premium.”² With respect to this group of smokers, the PATH Study Paper described similarities and differences in user characteristics, tobacco use patterns, and purchasing behaviors according to cigar type. Among the findings stated in this PATH Study Paper were that those who smoked “premium” cigars tended to report smoking them on fewer days compared with smokers of the other cigar types and reported consuming fewer cigars per day, on average, compared with smokers of other cigar types. In its conclusion, the PATH Study Paper highlighted the importance of adequately describing the cigar type studied and, where appropriate, differentiating results by cigar type.

When reviewing the PATH Study Paper and any other studies concerning cigars, it should be noted that tobacco research studies have not used a single, consistent definition of “premium” cigars. As demonstrated by FDA’s request for definitional information in this document, FDA considers it important to understand what definitions of premium cigar are used when analyzing and comparing results across studies and papers.

For the purposes of the questions in this ANPRM, “cigar” means a tobacco product that: (1) is not a cigarette and (2) is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco (see 21 CFR 1143.1).

II. Requests for Comments and Information

FDA is seeking comments, data, research results, and other information related to the following topics:

- Definition of premium cigars
- Use patterns of premium cigars

² While authors of the PATH Study Paper included FDA employees, the definition of premium cigars reported in the PATH Study Paper was used for research purposes only, and does not necessarily reflect FDA’s current thinking on regulatory policy.

- Public health considerations associated with premium cigars

Please provide any evidence or other information supporting your comments. Also, provide the definition of “premium cigar,” “youth,” and “young adult” used for the studies, information, or views provided in your responses.

A. Definition of Premium Cigars

1. Explain what data may be used to assess (a) the universe of cigar products that are currently available to consumers and (b) their relevant characteristics, including “premium” status.

How can available sources of information, such as manufacturer registrations and/or product listings with FDA, be used in this assessment?

2. 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.
 - r. Any action directed to consumers, by a retailer or manufacturer, such as through labeling, advertising, or marketing, which would reasonably be expected to result in consumers believing that the tobacco product is a premium cigar.
3. If available to you, provide annual sales data, including market size and volume, for products that you believe should be categorized as premium cigars, along with the information’s source and the definition of “premium cigar” used in the data provided.

B. Use Patterns of Premium Cigars

If available to you, provide the following information related to the use patterns of premium cigars generally and among youth and young adults specifically:

1. Studies or information regarding the potential role of premium cigars on tobacco initiation and progression to use of other tobacco products, especially compared and contrasted against the potential roles of other cigars.
2. Studies or information regarding behavioral data related to dual use of premium cigars and other tobacco products, especially compared and contrasted against dual use of other cigars.
3. Studies or information regarding the frequency and intensity (e.g., number of cigars smoked per day, depth of smoke inhalation, number of days smoking during a particular time period) of premium cigar use, especially compared and contrasted against other cigars.
4. Studies or information regarding the proportion of premium cigar smokers showing symptoms of dependence, especially compared and contrasted against other cigars.
5. Studies or information regarding the abuse liability of premium cigars compared with other tobacco products, especially compared and contrasted against other cigars.
6. Studies or information regarding the impact of premium cigar labeling, advertising, and marketing efforts on patterns of use, especially compared and contrasted against other cigars.
7. Information on the extent to which users of other tobacco products might switch to premium cigars if FDA were to exempt premium cigars from regulation or to regulate premium cigars differently from other cigars, and the measures that could be taken to prevent this from occurring. Where you discuss the potential effects of FDA regulating premium cigars differently from other cigars, please describe the specific different treatment that you envision.

C. Public Health Considerations

If available to you, provide the following information related to public health considerations:

1. Studies or information on any applicable manufacturing, marketing, sale, distribution, advertising, labeling, and/or packaging requirements and restrictions in the FD&C Act and its implementing regulations, and whether they should be applied differently to premium cigars compared to other tobacco products, including other cigars.
2. Studies or information regarding nicotine concentrations for premium cigars compared to other tobacco products, including other cigars.
3. Studies or information regarding the risk of oral cancer, esophageal cancer, laryngeal cancer, lung cancer, or any other form of cancer associated with premium cigars, especially compared and contrasted with risks for other cigars.
4. Studies or information regarding the risk of heart disease associated with premium cigars, especially compared and contrasted with risks for other cigars.
5. Studies or information regarding the risk of aortic aneurysm associated with premium cigars, especially compared and contrasted with risks for other cigars.
6. Studies or information regarding the risk of periodontal disease associated with premium cigars, especially compared and contrasted with risks for other cigars.
7. Studies or information regarding the risk of stroke associated with premium cigars, especially compared and contrasted with risks for other cigars.
8. Studies or information regarding the risk of chronic obstructive pulmonary disease associated with premium cigars, especially compared and contrasted with risks for other cigars.
9. Studies or information regarding risk of cancers of the mouth and throat for premium cigar users who do not inhale or who report that they do not inhale, especially compared and contrasted with risks for other cigars.

10. Studies or information on the impact of premium cigar use on other public health endpoints, including users and non-users, especially compared and contrasted with the impact of other cigars.
11. Studies or information regarding the addictiveness of premium cigars.
12. Studies or information regarding consumer perceptions of the health risks of premium cigars when compared to other tobacco products, including other cigars.
13. Studies or information regarding consumer perceptions of the addictiveness of premium cigars, especially compared and contrasted with perceptions for other cigars.
14. Studies or information on the required warning statements, shown below and which will be required to appear on cigar packaging and advertising in the near future (21 CFR 1143.5(a)(1)). Comment on whether any additional or alternative warning statements would be appropriate and provide your suggested language and any relevant studies or information.
 - a. WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
 - b. WARNING: Cigar smoking can cause lung cancer and heart disease.
 - c. WARNING: Cigars are not a safe alternative to cigarettes.
 - d. WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
 - e. WARNING: Cigar use while pregnant can harm you and your baby.;
 - or
 - SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.
 - f. WARNING: This product contains nicotine. Nicotine is an addictive chemical.

III. Reference

The following reference is on display in the Dockets Management Staff (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>. FDA has verified the website address, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. Corey, C.G., E. Holder-Hayes, A.B. Nguyen, et al. “ U.S. 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*, September 15, 2017, available at <https://academic.oup.com/ntr/article/4159211/U-S-adult-cigar-smoking-patterns-purchasing>.

Dated: March 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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