CALIFORNIA DEPARTMENT OF JUSTICE

TITLE 11. LAW
DIVISION 1. ATTORNEY GENERAL
CHAPTER 11. UNFLAVORED TOBACCO LIST

FINAL STATEMENT OF REASONS

UPDATE OF INITIAL STATEMENT OF REASONS

§ 942. Definitions

The Department added subdivision (e) to the definitions section. Subdivision (e) defines "Carton or Roll" as "a package that is marketed for retail sale to consumers and contains multiple identical Brand Styles that are individually marketed for retail sale to consumers." The definition is necessary to clarify what would qualify as a carton or roll, specifically made in response to comments asking whether certain product configurations would qualify as a carton or roll.

§ 945. Submission of product form

Subdivision (a) has been reorganized to reflect the addition of the "Carton or Roll" definition identified above. Specifically, subdivision (a)(1) was deleted because that definition is now incorporated in section 942, subdivision (e). Additionally, subdivision (a)(2) was deleted because that exception, along with what was previously subdivision (a)(3), is now incorporated in the new subdivision (a)(1), which provides that "A separate product form or variant form need not be submitted for a Carton or Roll of the Brand Style if that Carton or Roll has been identified on the product form or variant form for the Brand Style and all information on the product or variant form is completed for the Carton or Roll, including submission of a design file or photographs as described in subdivision (c)(7)."

Subdivision (a)(2) has been added to address questions and/or concerns raised through comments regarding when a modification to a brand style is substantive enough to require a new product or variant form. Subdivision (a)(2) omits the need for a new product or variant form where there are "variations in a Brand Style caused by changes in manufacturing materials or process that are not distinguishable by an ordinary consumer, where a product form or variant form for the Brand Style has already been submitted," and provides examples of such changes, including replacement of a cigarette's tipping paper with substantially identical tipping paper from a new source, a minor adjustment in a cigarette's size (e.g., 84 mm to 83.8 mm) that is not marketed differently, and minor changes resulting from a Brand Style being manufactured by hand, such as minor inconsistencies in the dimensions of a hand wrapped cigar. This new subdivision reflects the Department's acknowledgement that certain manufacturing changes that are not marketed differently and would not be distinguishable by an ordinary consumer do not constitute a new Brand Style that would require any new review from the Department through the submission of a new product or variant form. This standard also ensures that there are no flavor changes that would be distinguishable by an ordinary consumer, mirroring the language from the definition of

flavored tobacco product, which prohibits a constituent with "a taste or odor, distinguishable by an ordinary consumer either prior to or during the consumption of a tobacco product, other than the taste or odor of tobacco . . . ." (Health & Saf. Code, § 104559.5, subd. (a)(1), (a)(6).)

Subdivision (c)(8), which required written description of images depicted in the design file or photos, was removed from the regulations. During the initial review of products submitted under the emergency regulations, the Department determined that the written description did not reduce review time substantively, and there was confusion among regulated entities about the requirement in received comments. Accordingly, the requirement was removed.

The new subdivision (c)(8)(B)(i)(VII)(h) was added in response to public comment to allow applicants to enter information for a small category of products for which the Federal Drug Administration (FDA) has issued a rule, guidance, or other formal statement that the Brand Style does not require authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j after such authorization, approval, or order was sought. This category was inadvertently missed in the initial rulemaking draft but is needed to allow applicants to demonstrate that FDA authorization is not required for their product in this circumstance.

In subdivision (d), reference to "from the accessory, component, or part" was deleted. Because e-liquids may be considered a component or part in certain tobacco products, this deletion is intended to clarify that the Department will accept product forms or variant forms for e-liquids that contain 0% nicotine for inclusion on the UTL.

§ 946. Submission of variant form

A sentence was added to subdivision (a): "A UTL submission for a Variant is not complete until the UTL submission for the associated Predicate Brand Style is complete." This was added to clarify that applicants may not use the variant form unless a corresponding product form and UTL application have been completed. This is necessary because the purpose of the variant form's lower fee and reduced information requirement is that less review is required because applicable product information has already been reviewed via a product form. If the applicant has not completed the UTL application for the Predicate Brand Style, the Department lacks the necessary information on the variant form to determine applicability for placement on the UTL because the underlying product information on the product form has not been certified. Furthermore, the product information has not been previously reviewed for the Predicate Brand Style, negating the purpose of the lower fee.

Subdivision (d) was added to section 945 to clarify that a variant form is not required to be submitted for a variant that has the same external packaging as the Predicate Brand Style, or another Variant of the same Predicate Brand Style, but contains only different internal packaging, so long as that internal packaging does not implicitly or explicitly convey the presence of a flavor. The form is still needed when the internal packaging conveys the presence of a flavor because that packaging may alert the Department to a characterizing flavor. This clarification was added in response to submitted forms with varying internal packaging, which alerted the Department to this issue.

In subdivision (f), the Department added the requirement for multipacks to identify the name of the multipack. This was added after the Department reviewed thousands of applications and noted the pattern that multipacks are generally identified by a particular name, and inclusion of the name would assist with the ease of the use of the UTL.

A minor wording change was made to subdivision (g)(10) to clarify that the product form being referenced is that for the Predicate Brand Style(s).

Subdivision (g)(13), which required written description of images depicted in the design file or photos, was removed from the regulations. During the initial review of products submitted under the emergency regulations, the Department determined that the written description did not reduce review time substantively, and there was confusion among regulated entities regarding the requirement in received comments. Accordingly, the requirement was removed.

§ 948. Submission of variant form

Subdivision (c) adds language clarifying that the Attorney General shall not exclude a Brand Style from the UTL for lacking formal premarket authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j if the Brand Style is a Variant of a Predicate Brand Style that has been "placed on the UTL and a variant form for the Brand Style has been" submitted under Section 947. This language was added so that the proposed regulations conform with the emergency regulations, which exclude variants from the FDA requirements under subdivision (a) of Section 948, as long as the variant has a Predicate Brand Style that appears on the UTL. As explained in the Initial Statement of Reasons, "a Manufacturer or Importer's compliance with the FDA's deadlines for a Predicate Brand Style is sufficient indicia that the Manufacturer or Importer is engaging the FDA's premarket authorization process (which is designed to reduce the toll Tobacco Product use takes on public health) with respect to Variants of the Predicate Brand Style."

§ 952. Updates

A minor change was made to subdivision (a) to reference the exception provided in newly added subdivision (b)(2) of section 945, in addition to the exceptions already outlined in subdivision (b) of section 952, relating to the requirement for new product or variant forms when changes are made to an existing product.

Subdivision (b)(5) was removed from the regulations in response to comments that the subdivision was incongruous with the flavored tobacco product definition. The Department finds that receipt of applicant updates regarding common but minimal changes to a Brand Style, such as a change in the source of tipping paper, creates an administrative burden on applicants and on the Department that is not likely to justify the minimal value such updates would provide the Department in evaluating whether a product lacks a constituent that imparts a characterizing flavor. The removal of subdivision (b)(5) is consistent with the addition of subdivision (b)(2) to section 945, which, as explained above, reflects the Department's acknowledgement that certain manufacturing changes that are not marketed differently and are not distinguishable by an

ordinary consumer do not constitute a new Brand Style that would require any new review from the Department.

§ 953. Designation of Confidential Information

Language was added to subdivision (a) to clarify that information and documentation designated nonpublic and submitted under subdivisions (c)(8) and (c)(9) of Section 945, subdivision (g)(11) of Section 946, or subdivisions (b)(2) or (b)(3) of Section 952 shall be considered "additional information and documentation regarding a Brand Style's status with the FDA that is" confidential and proprietary under Health and Safety Code section 104559.1, subdivision (b)(3)(B), and not subject to disclosure under the California Public Records Act, except as specified in subdivisions (a)(1)-(a)(8).

Language was added to subdivision (a)(6) for consistency and clarity regarding the bases for which FDA authorization, approval, or order is not sought.

Subdivision (a)(8) was added to provide a publicly disclosable FDA status designation where an applicant indicates under subdivision (c)(8)(B) of Section 945 that formal authorization, approval, or order for the Brand Style has been sought under 21 U.S.C. sections 387e(j) or 387j, and also indicates under added subdivision (c)(8)(B)(i)(VII)(h) of Section 945 that the FDA has issued a rule, guidance, or other formal statement that the Brand Style does not require authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j.

CORRECTIONS AND NON-SUBSTANTIAL EDITS

A "non-substantial change is one that clarifies without materially altering the requirements, rights, responsibilities, conditions or prescriptions contained in the original text. (Cal. Code Regs., tit. 1, § 40.) The following minor additional issues were noted since publication of the Notice of Proposed Rulemaking and Initial Statement of Reasons:

§ 942. Definitions

The Department renumbered the remainder of the definitions section due to the addition of subdivision (e). The Department also updated the capitalization of "Carton or Roll" throughout the regulations to reflect the updated definition.

§ 944. Service Information and Time Limits

The Department added "is" to subdivision (c) as a correction and added "response" to subdivision (c) for grammar.

§ 945. Submission of product form

A parentheses was added to subdivision (c)(4) as a correction.

The Department made a minor wording change in subdivision (c)(6), changing “specified” to “identified,” for clarity.

Subdivisions and references to the subdivisions were renumbered throughout the regulations to reflect the deletion of subdivision (c)(8).

§ 946. Submission of variant form

Subdivisions and references to the subdivisions were renumbered to reflect the addition of subdivision (d), as well as the deletion of subdivision (g)(13).\

§ 947. Request for Placement on the Unflavored Tobacco List

A typo was corrected in subdivision (b)(5) to add the word “a” when referencing a packing slip.

§ 948. Submission of variant form

Minor wording changes were made to subdivisions (a)(1) and (a)(2) to insert a missing verb.

§ 951. Renewals

Minor wording changes were made to subdivision (c) for ease of reading and clarity.

§ 952. Updates

In subdivision (b)(1) and (b)(2) references to Section 945 were renumbered to reflect the deletion of subdivision (c)(8) of Section 945.

SUMMARY OF COMMENTS AND DEPARTMENT RESPONSES

The Department noticed the public on November 7, 2025, of the text of the proposed regulations and Initial Statement of Reasons. The Department held an in-person public hearing in Sacramento, California on December 23, 2025. A full transcript of that hearing is included in the rulemaking file as Exhibit 11. From November 7, 2025 to December 23, 2025, the Department received 19 written comments. The written comments are included in the rulemaking file as Exhibit 12.

In February 2026, the Department revised the proposed regulations to implement clarifications and changes proposed during the initial 45-day public comment period. The Text of the Proposed Regulations was modified on February 19, 2026, resulting in an additional 15-day public comment period that concluded on March 9, 2026. The Department received seven written comments during this comment period. The comments are included in the rulemaking file as Exhibit 13.

A summary of the comments received during the 45-day and 15-day comment periods, and the Department’s responses, are included in the rulemaking file as Appendix A.

45-Day Public Comment Period	
Written Comment #	**Name & Affiliation of Commenter**
1-1	Nathan Clay
2-1 to 2-3	Robert Michael Vanleeuwen
3-1 to 3-4	Alessandra Magnasco, California Fuels + Convenience Alliance
4-1 to 4-4	Deanna D. Clark, Clark-Esposito Law Firm, P.C.
5-1 to 5-4	Deanna D. Clark, Clark-Esposito Law Firm, P.C.
6-1 to 6-7	Paul W. Rodney, Arnold & Porter, representing Altria Client Services LLC, on behalf of Philip Morris USA Inc., John Middleton Co., U.S. Smokeless Tobacco Company LLC, NJOY, LLC, and Helix Innovations LLC
7-1 to 7-4	Adam Shepard, COO, Crowned Heads LLC
8-1 to 8-7	Robert C. Hsu, Lexint Law, PLC, on behalf of California Vape Products Supply Chain Association
9-1 to 9-3	Mike Szczepankiewicz
10-1	Denise Wiman, Stogies Louge, Inc.
11-1 to 11-9	Daniel Lance, Tabacalera Familia Disla S.A.
12-1 to 12-6	Andrew T. Mikac, Vice President & Assistance General Counsel – Regulatory, RAI Services Company
13-1 to 13-4	Michael Rosales, Managing Partner, RoMa Craft Tobac, LLC
14-1 to 14-32	Andrew Considine, Havan Style Inc., on behalf of California Premium Cigar Retailers Coalition
15-1 to 15-2	Mike Copperman, Executive Director, Cigar Rights of America
16-1 to 16-18	Joshua Habursky, The Premium Cigar Association
17-1 to 17-3	Scott Pearce, President, Cigar Association of America
18-1 to 18-4	Ian A. Reith, President, Dapper Cigar Company, LLC
19-1 to 19-4	Mo Maali, Owner, Patina Cigars

Public Hearing on December 23, 2025	
Name & Affiliation of Commenter	
20-1 to 20-3	Moe Assi
21-1	Daniel Andst, President, Tabacalera Familia Disla
22-1 to 22-6	Andrew Considine, Coalition Coordinator, California Premium Cigar Retailer Coalition
23-1	Jeff Fannin, Cigar Brand Owner, J. Torres Cigars

15-Day Public Comment Period	
Written Comment #	**Name of Commenter**
24-1	Brooklyn Tearney

25-1	Joshua M. Habursky, The Premium Cigar Association & Michael Copperman, Cigar Rights of America
26-1 to 26-4	Meghan Loper, Executive Director, California Distributors Association
27-1 to 27-2	Evan Spurrell
28-1 to 28-17	Andrew Considine, Coalition Coordinator, California Premium Cigar Retailers Coalition
29-1 to 29-13	Lauren Kass Lempert, JD, MPH; Pamela Ling, MD MPH; Stanton Glantz, PhD; Dorie Apollonio, PhD MPP; Stella Aguinaga Bialous, DrPH, FAAN; University of California San Francisco
30-1	Andrew T. Mikac, Vice President & Assistant General Counsel – Regulatory, RAI Services Company

LOCAL MANDATE DETERMINATION

The proposed regulation does not impose any mandate on local agencies or school districts.

ALTERNATIVES DETERMINATIONS

In accordance with Government Code section 11346.9, subdivision (a)(4), the Department has determined that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The Department has determined that the proposed regulation is the most effective and least burdensome way for the Department to determine those tobacco products that lack a characterizing flavor and are eligible for placement on the Unflavored Tobacco List.

ALTERNATIVES THAT WOULD LESSEN ADVERSE ECONOMIC IMPACT ON SMALL BUSINESSES

Except as set forth and discussed in the summary and responses to comments, no other alternatives were proposed or otherwise brought to the Department's attention.

DOCUMENTS INCORPORATED BY REFERENCE

No documents are incorporated by reference.

NON-DUPLICATION

Some of the regulations may repeat or rephrase in whole or in part a state or federal statute or regulation. This was necessary to satisfy the clarity standard set forth in Government Code section 11349.1, subdivision (a)(3).