CALIFORNIA DEPARTMENT OF JUSTICE

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

August 6, 2025

FINDING OF EMERGENCY

Pursuant to the requirements of Government Code section 11346.1, subdivision (a)(1), the Department of Justice (Department) is providing notice of proposed emergency adoption of regulations regarding the establishment, maintenance, and enforcement of a list of unflavored tobacco products pursuant to Assembly Bill 3218, which requires the Attorney General to establish and maintain an unflavored tobacco products list on or before December 31, 2025. The Department finds that an emergency exists, and that the immediate adoption of Title 11, Division 1, Chapter 11, Sections 942 through 957 is necessary to avoid serious harm to the public peace, health and safety, and general welfare.

SUBMISSION OF COMMENTS

Government Code section 11346.1, subdivision (a)(2) requires that, at least five working days prior to the submission of the proposed emergency action to the Office of Administrative Law (OAL), the Department provide a notice of proposed emergency action (Finding of Emergency) and Proposed Text to every person who has filed a request for notice of regulatory action with the Department. After submission of the proposed emergency regulation to the OAL, the OAL shall allow interested persons five calendar days to submit comments on the proposed emergency regulation as set forth in Government Code section 11349.6.

The Proposed Text of the emergency regulation and the Finding of Emergency are posted on the Department's website at https://oag.ca.gov/regulations.

The Department plans to file the emergency rulemaking package with the OAL at least five working days from the date provided at the top of this notice. If you would like to comment on the Finding of Emergency or the Proposed Text, those comments must be made in writing only, must contain a notation that identifies the emergency regulation to which they relate, and must be received by both the Department and the OAL within five calendar days of the Department's filing with the OAL. The Department may respond to comments at its discretion.

Send comments simultaneously to:

Department of Justice
Taylor Ann Whittemore
1515 Clay Street, P.O. Box 70550
Oakland, CA 94612
UTLregulations@doj.ca.gov

and

Office of Administrative Law
300 Capitol Mall, Suite 1250
Sacramento, CA 95814

EXPRESS STATEMENT OF EMERGENCY

Assembly Bill 3218, which went into effect on January 1, 2025, requires the Attorney General to establish and maintain an unflavored tobacco products list on or before December 31, 2025. This proposed rulemaking will implement Assembly Bill 3218, in part, by describing how manufacturers and importers of unflavored tobacco products may apply for the placement of their products on the unflavored tobacco product list, what information those manufacturers and importers must provide, the timing for applications and responses, and the administrative procedure for issuing and appealing penalties against wholesalers, distributors, and delivery sellers that sell products not appearing on the list.

The proposed regulations are, by legislative mandate, deemed emergency regulations necessary for the immediate preservation of the public health, safety, and welfare under the governing statute. (Health & Saf. Code, § 104559.1, subd. (q).)

INFORMATION DIGEST/POLICY STATEMENT OVERVIEW

Summary of Existing Laws and Regulations:

A. Senate Bill 793

Senate Bill 793 banned flavored tobacco products (subject to certain exceptions) and tobacco product flavor enhancers in California. (Health & Saf. Code, § 104559.5.) A flavored tobacco product is a "tobacco product that contains a constituent that imparts a characterizing flavor." (*Id*., subd. (a)(6).) A "characterizing flavor" is "a taste or odor . . . other than the taste or odor of tobacco." (*Id*., subd. (a)(1).) Similarly, a tobacco product flavor enhancer is "a product designed, manufactured, produced, marketed, or sold to produce a characterizing flavor when added to a tobacco product." (*Id*., subd. (a)(18).)

B. Assembly Bill 3218

Assembly Bill 3218 amended the flavor ban put in place by Senate Bill 793 and expanded on it. (Bus. & Prof. Code, §§ 22978.3, 22980, 22990; Health & Saf. Code, §§ 104559.1, 104559.5; Rev. & Tax. Code, § 30101.7.) It established the Unflavored Tobacco List (UTL), a list of covered tobacco products that are permissibly unflavored under the law. (Health & Saf. Code, § 104559.1, subd. (a).) Products not appearing on the list will be subject to seizure, and the Attorney General, the California Department of Public Health, and state and local law enforcement agencies are authorized to seek civil penalties against retailers of products not appearing on the list. (Health & Saf. Code, §§ 104559.1, subd. (g), 104559.5, subd. (b)(1); Bus. & Prof. Code, § 22974.2, subd. (a).) The Attorney General may also seek civil penalties against distributors, wholesalers, and delivery sellers for violations. (Health & Saf. Code, § 104559.1, subd. (o)(3).) Furthermore, the bill revised the definition of characterizing flavor to specifically

incorporate cooling sensations distinguishable by an ordinary consumer. (Health & Saf. Code, § 104559.5, subd. (a)(1).)

Effect of the Proposed Rulemaking:

This proposed rulemaking will implement Assembly Bill 3218 (Health & Saf. Code, § 104559.1). It describes how manufacturers and importers of unflavored tobacco products may apply for the placement of their products on the UTL, what information those manufacturers and importers must provide, and the timing for applications and responses. The rulemaking also establishes fees for initial and renewed placement on the list. Finally, it describes how civil penalties against distributors, wholesalers, and delivery sellers of products not appearing on the UTL may be assessed and appealed.

Anticipated Benefits of the Proposed Regulations:

By implementing the UTL, this rulemaking will aid with enforcement and seizure of illegal flavored tobacco products by providing clarity on what products are permissibly unflavored. This will benefit the health and welfare of California residents by reducing the amount of youth-appealing flavored tobacco products available on the market. It will also provide clarity to manufacturers, importers, distributors, wholesalers, and retailers regarding what products are "unflavored" under state law and may be sold (provided such products comply with other applicable laws), allowing these entities to market or purchase products with more certainty.

Comparable Federal Regulations:

There are no existing federal regulations or statutes comparable to the proposed regulations.

Determination of Inconsistency/Incompatibility with Existing State Regulations:

The Department has determined that the proposed regulations are not inconsistent or incompatible with existing state regulations. After conducting a review for any regulations that would relate to or affect this area, the Department has concluded that these are the only regulations that concern flavored tobacco products.

Forms Incorporated by Reference: None.

Other Statutory Requirements: None.

SPECIFIC FACTS DEMONSTRATING NEED FOR IMMEDIATE ACTION

Immediate action is required to avoid serious harm to the public peace, health and safety, and general welfare because Assembly Bill 3218, which went into effect on January 1, 2025, requires the Attorney General to establish and maintain an unflavored tobacco products list on or before December 31, 2025. This proposed rulemaking will implement Assembly Bill 3218 (Health & Saf. Code, § 104559.1) in part by describing how manufacturers and importers of unflavored

tobacco products may apply for the placement of their products on the UTL, what information those manufacturers and importers must provide, and the timing for applications and responses.

Purpose and Necessity of Each Provision

§ 942. Definitions

Section 942 defines nineteen (19) key terms that are used in the proposed regulations. The definitions are necessary to avoid any confusion that might result if these terms were not defined and to ensure uniform application throughout the regulations.

Subdivision (a) defines "Applicant" to encompass Manufacturers and Importers. This definition is necessary to identify the entities that are permitted to apply for placement of a tobacco product on the UTL. (Health & Saf. Code, § 104559.1, subd. (b)(1).)

Subdivision (b) defines "Attorney General" as the Attorney General of the State of California or any employee of the Attorney General acting under the authority of the Attorney General. This definition is necessary to clarify that the term encompasses those who act under the authority of the Attorney General.

Subdivision (c) defines "Brand Style" to have the same meaning as set forth in Health and Safety Code section 104559.1, subdivision (s)(1). This definition is necessary to clarify what characteristics differentiate tobacco products of the same brand as well as what products are considered distinct for the purposes of the UTL and require a separate application for listing on the UTL.

Subdivision (d) defines "Cannabis" to have the same meaning as set forth in Business and Professions Code section 26001, subdivision (f). Including this statutory definition in the regulations is necessary for ease of reference and to provide consistency across statutory schemes.

Subdivision (e) defines "Certifying User" as an agent who has authority to submit UTL Applications, Renewal Applications, updates, and make binding certifications on behalf of an Applicant. This definition is necessary to clarify who may submit applications for placement on the UTL and other certifications on behalf of an Applicant.

Subdivisions (f) defines "Characterizing Flavor" to have the same meaning as set forth in Health and Safety Code section 104559.1, subdivision (s)(2), and defines a Brand Style that "lacks a Characterizing Flavor" as a tobacco product that lacks any Constituent that imparts a Characterizing Flavor. These definitions are necessary to clarify what constitutes a flavored product for purposes of the UTL.

Subdivision (g) defines "Constituent" to have the same meaning as set forth in Health and Safety Code section 104559.5, subdivision (a)(2). This definition is necessary to clarify what constitutes a flavored product for purposes of the UTL.

Subdivision (h) defines “Importer” as the same meaning as set forth in Revenue and Taxation Code section 30019. This definition is necessary to identify what entities may apply for placement of a tobacco product on the UTL and to provide consistency across statutory schemes regarding tobacco products.

Subdivision (j) defines “Initial Unflavored Tobacco List Deadline” as either September 1, 2025, or 45 days after these regulations are adopted, whichever is later. Creating this definition makes the regulations easier to read.

Subdivision (k) defines “Initial Unflavored Tobacco List Publication Date” as the date the UTL is published. Creating this definition makes the regulations easier to read.

Subdivision (l) defines “Manufacturer” to have the same meaning as set forth in Business and Professions Code section 22971, subdivision (m). This definition is necessary to identify what entities may apply to the UTL and to provide consistency across statutory schemes regarding tobacco products.

Subdivision (m) defines “Marketing Descriptor” as a descriptor that distinguishes Brand Styles within a brand or Sub-Brand. This definition is necessary to clarify what tobacco products are considered distinct for the purposes of the UTL. It is also necessary to ensure the product name used for identification encompasses all identifying features of the product.

Subdivision (n) defines “Predicate Brand Style” as a Brand Style for which an Applicant has previously completed a Product Form. Creating this definition makes the regulations easier to read. This definition is necessary to clarify that Applicants may only submit a Variant Form for products that already have a Product Form completed.

Subdivision (o) defines “Sub-Brand” as a secondary brand that identifies the Brand Style and is used across a product line. This definition is necessary to clarify what tobacco products are considered distinct for the purposes of the UTL and to identify the product for which the Applicant has submitted an application.

Subdivision (p) defines “Tobacco Product” to have the same meaning as set forth in Health and Safety Code section 104559.1, subdivision (s)(3). Including this statutory definition in the regulations is necessary for ease of reference.

Subdivision (q) defines “Unflavored Tobacco List” or “UTL” as the Unflavored Tobacco List described in Health and Safety Code section 104559.1, subdivision (a). The Department adopts the statutory definition of Unflavored Tobacco List and establishes an abbreviation for ease of reading.

Subdivision (r) defines “User” as an agent authorized by an Applicant to view account information and draft and submit Product Forms and Variant Forms. This definition is necessary to clarify the level of permissions certain agents have in providing information on behalf of Applicants on the web portal used to submit applications for placement on the UTL.

Subdivision (s) defines "Variant" as a Brand Style that is identical to that Predicate Brand Style in all respects, with the exception of the universal product code, manufacturing stock keeping unit number, packaging or labeling (including multipacks), inclusion (or non-inclusion) of an electronic device (as part of a multipack), or product count per package, and clarifies that "Variant" does not include any Brand Style with a packaging difference that imparts flavor. This definition is necessary to delineate what constitutes a Variant, and what would instead require a new Product Form. It also is included for ease of reading.

§ 943. Applicant Information and Account Creation

Health and Safety Code section 1045591.1, subdivision (b), requires "[e]very manufacturer and importer of tobacco products" to submit to the Attorney General the unflavored tobacco products that they manufacture or import for sale or distribution in or into California and information about each of those products. Section 943 describes how Applicants may create accounts on the Attorney General's web portal, where UTL materials and applications will be submitted.

Subdivision (a) requires UTL applications to be submitted through the Attorney General's UTL web portal. This requirement is necessary to establish an efficient process for the submission and review of UTL applications and to provide the Attorney General with sufficient information to evaluate placement of a product on the UTL.

Subdivision (b) requires Users to create an Applicant account and a User account in order to submit an application and explains where such an account may be created. This requirement is needed to protect the Applicant from unauthorized submissions in their name and to organize the applications by Applicant.

Subdivisions (c)(1) through (c)(2) require Users to agree to terms of use when creating an account on the website: that Applicant is authorized to use the UTL web portal for the purposes of providing Brand Style information to the Attorney General and/or for applying for placement on the UTL in order to comply with California laws and regulations; if Applicant becomes aware of an unauthorized person obtaining access to their Applicant account, Applicant will notify the Attorney General; and all submissions made via the UTL web portal will be electronically dated. These terms of use are necessary to protect against unauthorized use of the UTL web portal.

Subdivisions (d)(1) through (d)(10) specify the information that must be provided in order to create an Applicant account, including: name, California Department of Tax and Fee Administration license number, Federal employer identification number, Alcohol and Tobacco Tax and Trade Bureau Permit Number, mailing address, email address where Applicants will receive communications related to their submissions, principal place of business, website address, name and contact information of Applicant's registered agent for service of process, and whether Applicant is a Manufacturer or Importer. This information is required to ensure proper identification of Applicants. The email address is where Applicants will receive communications related to UTL web portal submissions, and Applicants' registered agents for service of process are required to ensure that Applicants timely receive communications and notices from the Attorney General about its UTL applications, citations, or proposed actions related to its products.

Subdivision (d)(11) requires uploading a signed letter from Applicant on Applicant's official letterhead authorizing User to create that account, and it requires Applicant to authorize at least one Certifying User on the account. Subdivision (d)(11) further specifies that Applicants may authorize multiple Users in one letter, but must identify each User's permissions level by stating whether they are a Certifying User or other User. The subdivision further permits Applicants to submit additional letters complying with the same requirements to authorize, remove, or change the status of its Users. These requirements are needed in order to protect Applicants from unauthorized use, submissions, or certifications on their behalf.

Subdivision (e) requires each authorized User to create an individual User account and to provide the User's email address, name, title and phone number. This information is necessary to allow Users access to corresponding Applicant accounts and ensure that Users receive communications from the Attorney General related to the Applicant's account.

Subdivision (f) requires notification of changes to information in the Applicant account. The Attorney General has determined that a 15-day deadline is reasonable and necessary to ensure that the Attorney General has accurate and updated information regarding Applicants.

§ 944. Service Information and Time Limits

Section 944 establishes the means by which the Attorney General will communicate with Applicants and how time will be calculated for purposes of time limits in the regulations.

Subdivision (a) requires all communications described in Sections 943 through 952 of this chapter to be made electronically and explains that time limits commence on the day a communication is sent to the email address specified in Applicant's account on the Attorney General's UTL web portal or to the Attorney General at UTLinbox@doj.ca.gov. Subdivision (a) defines business days for the purposes of computation of time under this chapter and notifies Applicants that when the last day to perform or complete any act provided for in this chapter falls on Saturday, Sunday, or holiday set forth in Government Code section 6700, the time computation excludes that day and includes the next business day. This is necessary to notify Applicants about how the Attorney General will communicate with them about their submissions related to placement on the UTL and to explain how time limits under this chapter will be calculated.

Subdivision (b) provides that the Attorney General may extend the time limits set forth in Section 943 through 952 for good cause. The necessity of this subdivision is to allow the Attorney General to accommodate unforeseen or special circumstances.

§ 945. Submission of Product Form

In order to request that their product be included on the UTL, Manufacturers and Importers of Brand Styles for sale or distribution in California that lack a Characterizing Flavor must submit to the Attorney General information for each Brand Style that describes the product and product category, and whether authorization, approval or order from the FDA has been sought and if so,

the status of that request. (See Health and Saf. Code, § 104559.1, subd. (b)(1).) Section 945 establishes the process by which Applicants can submit tobacco product information to the Attorney General. This process is necessary to provide the Attorney General with sufficient information to evaluate a product's placement on the UTL and for administrative efficiency.

Subdivision (a) requires that a Product Form or Variant Form for the applicable Brand Style must be submitted before Applicants may apply to place a Brand Style on the UTL. Subdivision (a) further clarifies that a Product Form is not a UTL application, and that a UTL application must also be completed on the UTL web portal, as outlined in Section 947, in order for the Brand Style to be considered for placement on the UTL. Requiring submission of the prescribed forms ensures that Applicants provide the Attorney General with sufficient information to evaluate a product's placement on the UTL. Separating the Product and Variant Forms from the UTL application allows Applicants to pay fees and prepare samples in one batch while submitting a UTL application after the underlying product information has been populated through the Product or Variant Forms.

Subdivision (b) requires Product Forms to be submitted through an Applicant account on the Attorney General's UTL web portal. Requiring submission of the prescribed forms through the UTL web portal ensures an efficient means by which the Attorney General may obtain the required information from Applicants. Subdivision (b) also provides that the Attorney General may permit exceptions to submission via the web portal, on a case-by-case basis. This exception is needed to allow the Attorney General to address unforeseen circumstances.

Subdivisions (c)(1), (c)(2), and (c)(5) require identifying information about the Brand Style, including the brand name, Sub-Brand name, Marketing Descriptor, universal product code, manufacturing stock keeping unit number, and type of product unit as described on the Brand Style's package. This information is necessary to identify the specific product for which the Product Form is submitted so that it can be properly identified by the Attorney General, local enforcement staff, and the public, if it is placed on the UTL.

Subdivision (c)(3) requires information regarding the trademark holder. This information is needed to distinguish among Brand Styles and identify the parties responsible for a Brand Style.

Subdivisions (c)(4)(A) through (c)(4)(E), and (c)(6) require information about the product, including the tobacco product category and subcategory in which it falls, and based upon the categories and subcategory the product falls under, details about the product, including: product count per package; volume; weight; length; circumference diameter, or ring gauge; fill type; whether the product contains added nicotine; the type of added nicotine, including tobacco-derived nicotine, synthetic nicotine, nicotinic alkaloid or nicotine analog, or other type of nicotine; a description of the nicotine analog, nicotinic alkaloid or other type of nicotine; and the concentration or strength a of nicotine in the product; whether the product contains Cannabis; whether the product contains a capsule; wrapper type; device type; package type; for e-cigarettes and vapes, the device name, whether it contains a lithium-ion battery, and battery capacity; and for e-liquids and heated tobacco products, the name of the device it is intended to be used in. This information is necessary to differentiate between tobacco products and fully describe the Brand Style as required by Health and Safety Code section 104559.1, subdivision (b)(1)(A), as

well as to provide the Attorney General with sufficient information to evaluate whether the Brand Style is eligible and qualified for placement on the UTL.

Subdivision (c)(7) requires a design file that contains all visual information needed to render or show every non-blank side of the packaging for the Brand Style, or, alternatively, if no design file is available, photographs of every non-blank side of the packaging. Subdivision (c)(7) further specifies that the design file or photographs must include images of any carton or roll associated with the Brand Style. This information is necessary for the Attorney General to assess the Brand Style's packaging for indications that the product has a Characterizing Flavor.

Subdivision (c)(8) requires a written description of images depicted in the design file or photos provided under subdivision (c)(7). These descriptions must include any images on the package that correspond to a flavor and any written descriptors of flavors on the product packaging. This information is necessary for administrative efficiency in processing images to assist the Attorney General's assessment of the Brand Style's packaging for indications that the product has a Characterizing Flavor.

Subdivisions (c)(9) through (c)(10) require information about the status of the Brand Style with the FDA. FDA describes the review process as follows:

> Before introducing a new tobacco product to the U.S. market, a company must generally submit a marketing application to the FDA and receive authorization. A "new tobacco product" is defined as any product not commercially marketed in the U.S. as of February 15, 2007, or the modification of a tobacco product where the modified product was commercially marketed in the U.S. after February 15, 2007. These new products and their applications are comprehensively evaluated by FDA scientists, who determine whether or not the application proves the new tobacco product meets the appropriate statutory standards.[1]

FDA describes the three pathways for new tobacco products to obtain authorization, approval, or order for marketing in the United States under 21 U.S.C. sections 387e(j) and 387j as follows:

1. Premarket Tobacco Product Application (PMTA) under 21 U.S.C. section 387j: "A PMTA must demonstrate the new tobacco product would be 'appropriate for the protection of the public health' and takes into account the increased or decreased likelihood that existing users of tobacco products will stop using such products, as well as the increased or decreased likelihood that those who do not use tobacco products will start using such products."[2]
2. Substantial Equivalence (SE) under 21 U.S.C. section 387e(j): "A new tobacco product may be found 'substantially equivalent,' to a 'predicate' product by demonstrating the

[1] Food & Drug Administration, "Market and Distribute a Tobacco Product," <https://www.fda.gov/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product> (as of July 9, 2025) (footnotes omitted).
[2] Food & Drug Administration, "Market and Distribute a Tobacco Product," <https://www.fda.gov/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product> (as of July 9, 2025) (footnotes omitted).

product has the same characteristics as that predicate product, or if the product has different characteristics, by demonstrating that the new product does not raise different questions of public health than the predicate product."[3]

3. Exemption from Substantial Equivalence (EX REQ) under 21 U.S.C. section 387e(j)(3): "A tobacco product that is modified by adding or deleting a tobacco additive, or by increasing or decreasing the quantity of an existing tobacco additive may be considered for an exemption from demonstrating substantial equivalence."[4]

Assembly Bill 3218 requires Manufacturers and Importers to describe, for each Brand Style, if formal authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j was sought and the status of any such request (Health & Saf. Code, § 104559.1, subd. (b)(1)(B)); provides the Attorney General authority to request additional information regarding the Brand Style's status with the FDA (*id*., at subd. (b)(3)(A)); and provides the Attorney General discretion to exclude any Brand Style from the UTL that is required to obtain but has not received formal authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j (*id*., at subd. (e)). Section 948 of this chapter identifies the circumstances in which the Attorney General intends to exercise discretion to exclude Brand Styles from the UTL under Health and Safety Code section 104559.1, subdivision (e). The information required under subdivisions (c)(9) through (10) is needed to establish and verify a Brand Style's status with the FDA and whether that status renders the Brand Style ineligible for listing on the UTL under Section 948.

Subdivision (c)(9) requires Applicants to specify whether a Brand Style has received a formal authorization, approval, or order from the FDA under 21 U.S.C. sections 387e(j) or 387j.

If there is an affirmative response to (c)(9), subdivisions (c)(9)(A)(i) through (c)(9)(A)(iii) require the identification of pathways under 21 U.S.C. sections 387e(j) or 387j for which the FDA provided authorization, approval, or order; the date of that authorization, approval, or order; and documentation from the FDA establishing that the authorization, approval, or order was provided.

If the response to subdivision (c)(9) is that no formal authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j has been received for the Brand Style, subdivision (c)(9)(B) requires Applicants to answer whether such authorization, approval, or order was sought.

If there is an affirmative response to (c)(9)(B), subdivisions (c)(9)(B)(i)(I) through (c)(9)(B)(i)(VII) require information the Attorney General needs to determine the Brand Style's status with the FDA in light of the FDA's premarket review rules, including: the pathways under 21 U.S.C. sections 387e(j) or 387j for which authorization, approval, or order for the Brand Style has been sought;[5] whether, for Brand Styles that contain nicotine that is not derived from

[3] *Ibid*.
[4] *Ibid*.
[5] See U.S. Food and Drug Administration, "Tobacco Product Marketing Orders," <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders> (as of July 9, 2025).

tobacco, the Brand Style was commercially marketed as of April 14, 2022;[6] whether, for Brand Styles that contain nicotine derived from tobacco and that do not fall into the product categories of Cigarettes, Roll-your-own Tobacco Filler, or Smokeless Tobacco Products, the Brand Style was commercially marketed as of August 8, 2016;[7] the date of the submission to the FDA of each request for authorization, approval, or order for the Brand Style under 21 U.S.C. sections 387e(j) or 387j, so the Attorney General may ascertain whether that submission was timely; whether the submitted request for authorization, approval, or order for the Brand Style under 21 U.S.C. sections 387e(j) or 387j was accepted by the FDA for filing or review;[8] the most recent FDA-assigned Submission Tracking Number for each request for FDA authorization, approval, or order associated with the Brand Style under 21 U.S.C. sections 387e(j) or 387j, so the Attorney General may verify Applicant representations about FDA status; the date of specified negative actions on a request for FDA authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j, which could provide the Attorney General a basis for excluding a Brand Style from the UTL under Section 948 of this chapter; information about any stay, recission, or vacatur by the FDA or a court of competent jurisdiction of a negative action on a request for FDA authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j, which, under Section 948, could divest the Attorney General's authority to exclude from the UTL a product that received a negative action on a request for FDA authorization, approval, or order; and whether a provisional Substantial Equivalence report for the Brand Style submitted under 21 U.S.C. section 387j(a)(2)(B) is under review by the FDA or was removed from review by the FDA, because Brand Styles with such provisional status do not require formal premarket authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j and therefore are not excludable under Section 948.

If the response to (c)(9)(B) is that formal authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j was not sought, subdivisions (c)(9)(B)(ii)(I) through (c)(9)(B)(ii)(IV) require information about the reason(s) why authorization was not sought: the Brand Style does

[6] See U.S. Food and Drug Administration, "Requirements for Products Made with Non-Tobacco Nicotine Take Effect April 14," <https://www.fda.gov/tobacco-products/ctp-newsroom/requirements-products-made-non-tobacco-nicotine-take-effect-april-14#:~:text=Further%2C%20manufacturers%20of%20NTN%20products,%2C%20May%2013%2C%202022).> ["manufacturers of NTN [non-tobacco nicotine] products who wish to market their products are required to submit a premarket application and obtain FDA authorization to market their product, or they will be subject to FDA enforcement; the deadline for premarket application submissions for currently marketed NTN products is Saturday, May 14, 2022"] (as of July 9, 2025).

[7] See U.S. Food and Drug Administration, Deeming Rule, 81 Fed. Reg. 28973–29104 (May 10, 2016).

[8] See, e.g., 21 C.F.R. § 1105.10 [identifying reasons for which "FDA will refuse to accept for review, as soon as practicable, a premarket tobacco product application, modified risk tobacco product application, substantial equivalence application, or exemption request or subsequent abbreviated report"].

not contain nicotine from any source;[9] the Brand Style is a pre-existing product,[10] which would require the identification of any associated Voluntary Pre-Existing Tobacco Product Status Determination information from the FDA so the Attorney General may validate the Applicant's representation;[11] 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, which would serve as a basis for not excluding the Brand Style under subdivision (b)(1) of Section 948; and/or that another reason exists for why authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j for the Brand Style was not sought. This information is necessary for the Attorney General to ascertain whether the Brand Style should be excluded under Section 948 because the Brand Style required, but did not receive formal premarket authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j.

Subdivision (c)(10) requires FDA documentation sufficient to identify the Brand Style's current status under a marketing pathway or under the FDA's Voluntary Pre-Existing Status Determinations Request process, so that the Attorney General may verify representations made about any such status identified in response to the information sought in subdivision (c)(9).

Subdivision (c)(11) requires Applicants to submit every determination made by another government agency regarding flavor in the Brand Style. This information is necessary so the Attorney General can assess whether the product has a Characterizing Flavor.

Subdivision (c)(12) allows Applicants to provide additional information or comments regarding the Brand Style that the Applicant considers relevant to the Attorney General's determination as to whether or not the Brand Style is an unflavored tobacco product under Health and Safety Code section 104559.5. This option is necessary to provide the Attorney General with information sufficient to evaluate the Applicant's UTL application.

Subdivision (d) clarifies that Product Forms and Variants Forms will not be accepted for specified devices, accessories, components, or parts that do not contain nicotine or liquid intended to be vaporized and inhaled, as these products are not eligible for inclusion on the UTL. (Health & Saf. Code, §§ 104559.1, subd. (s)(3), 104559.5, subd. (a)(17)(A).)

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[9] See U.S. Food and Drug Administration, "Regulation and Enforcement of Non-Tobacco Nicotine (NTN) Products," <https://www.fda.gov/tobacco-products/products-ingredients-components/regulation-and-enforcement-non-tobacco-nicotine-ntn-products#:~:text=In%20response%20to%20the%20increase,any%20source%2C%20including%20synthetic%20nicotine.> ["In response to the increase of NTN in popular tobacco products, Congress passed a federal law which went into effect on April 14, 2022, clarifying FDA's authority to regulate tobacco products containing nicotine from any source, including synthetic nicotine."] (as of July 9, 2025).

[10] See U.S. Food and Drug Administration, "Tobacco Product Marketing Orders," < https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders#:~:text=A%20pre%2Dexisting%20tobacco%20product%20is%20any%20tobacco%20product%20(including,on%E2%80%9D%20or%20before%20that%20date.> ["Pre-existing tobacco products … do not require premarket authorization to be legally marketed."] (as of July 9, 2025).

[11] See U.S. Food and Drug Administration, "Pre-Existing Tobacco Products," < https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/pre-existing-tobacco-products> (as of July 9, 2025).

§ 946. Submission of Variant Form

Section 946 establishes the process by which an Applicant may submit tobacco product information for Brand Styles that may be considered a Variant—a type of Brand Style that is identical in all respects, with the exception of the universal product code, manufacturing stock keeping unit number, packaging or labeling (including multipacks), inclusion (or non-inclusion) of a device (as part of a multipack), or product count per package, to a Predicate Brand Style for which a Product Form has already been submitted. This is necessary because, even though a product may be a Variant of another tobacco product that has been placed on the UTL, or for which a UTL application is pending, Manufacturers and Importers must submit to the Attorney General a certification for each Brand Style for sale or distribution in California that lacks a Characterizing Flavor describing the product and product category and whether authorization, approval, or order from the FDA has been sought, and, if so, the status of that request. (Health & Saf. Code, § 104559.1, subd. (b)(1).) Because some of the information applicable to a Variant overlaps with that of a Predicate Brand Style, the process for Variants is streamlined to provide a more efficient review.

Subdivision (a) describes that a Variant Form may be submitted in lieu of a Product Form if the Brand Style is a Variant and meets the criteria of subdivision (c). Variants that meet the criteria specified in subdivision (c) share core similarities with Predicate Brand Styles, for which a Product Form has already been submitted. Because the Attorney General has already received information pertaining to the Variant through the Applicant's submission of a Product Form for the Predicate Brand Style, the Variant Form requires less product information than a Product Form, thereby streamlining the Attorney General's review. This streamlined review is necessary for efficient use of Attorney General resources and also permits the Attorney General to charge a reduced fee for Variants (when submitted in a UTL application), since they require fewer resources.

Subdivision (b) requires that a Variant Form be submitted through the Attorney General's UTL web portal and allows the Attorney General to permit exceptions to web submission. Requiring submission of the prescribed forms through the UTL web portal ensures an efficient means by which the Attorney General may obtain the required information from Applicants. Subdivision (b) also provides that the Attorney General may permit exceptions to submission via the web portal on a case-by-case basis. This exception is needed to allow for the Attorney General to address unforeseen circumstances.

Subdivisions (c)(1) through (c)(7) list the types of Variants for which the Variant Form may be used: (1) Variants with packaging designed for other markets, including exports; (2) Variants with different packaging or different product count per package, unless the packaging difference imparts flavor; (3) Variants with promotional packaging or discount Brand Styles; (4) Language on packaging different from Predicate Brand Style, e.g. French or Spanish; (5) Variants with a different universal product code or stock keeping unit; (6) Multipacks; and (7) Multipacks with devices. Because the Variant Form does not require as much product information as a Product Form, it is necessary to restrict the availability of the Variant Form to those types where differences from the Predicate Brand Style are minimal and should not affect the product's

flavor. Accordingly, the types of Variants for which use of the Variant Form is permitted is restricted to those with differences in packaging and count, and those with different inventory codes. These types of Variants require a more limited review by the Attorney General focused primarily on the packaging, to determine whether the packaging indicates the presence of a Characterizing Flavor, because the Attorney General can review the underlying product based on the Product Form submitted for the Predicate Brand Style.

Subdivision (d) requires the Applicant to identify what type of Variant the Brand Style is, and if it is a multipack, whether the multipack has a device. This is necessary because the information required for the Attorney General to assess placement on the UTL differs based on Variant type.

Subdivisions (e)(1) through (7) require information about Brand Style depending on the type of Variant it is: for Variants with packaging designed for other markets, such as exports, a description of those other markets; for Variants with different packing or product count per package, a description of the packaging and the difference in product count; for Variants with promotional packaging or discount Brand Styles, a description of the promotion or discount; for Variants with packaging in a different language, the language used must be specified; for Variants that are a multipack, a description of the Variant's packaging and for Variants that are a multipack with a device, a description of the Variant's packaging, the device name and type, whether the device contains a lithium ion battery, and the battery's capacity. The requested information is necessary to identify the product and distinguish it from the Predicate Brand Style. Information regarding the device is necessary because when the device is separable from the product, information about the device would not have been provided in the Predicate Brand Style's Product Form, but is necessary to fully describe the Brand Style, as required by Health and Safety Code section 104559.1, subdivision (b)(1)(A).

Subdivision (e)(8) requires Applicants to provide the Predicate Brand Style(s) to which a Variant is related. This is necessary because the Variant Form does not require all information that a Product Form does; information regarding the Predicate Brand Style(s) permits the Attorney General to fully identify the Variant Brand Style and determine whether it has a Characterizing Flavor.

Subdivision (e)(9) requires Applicants to confirm whether the carton or roll that the Variant comes in is different from that used for the Predicate Brand Style. This is required because if the carton or roll is different, the Attorney General needs to assess the Variant's and the Predicate Brand Style's packaging individually to determine whether the packaging for either product indicates the presence of a Characterizing Flavor.

Subdivisions (e)(10) requires the universal product codes that identify the Variant and any associated carton or roll, or, if the Variant does not have a universal product code, the manufacturing stock keeping unit number. This information is needed to identify the specific product for which the Variant Form is submitted so that it can be properly identified by the Attorney General, local enforcement staff, and the public, if it is placed on the UTL.

Subdivision (e)(11) requires information about whether a formal authorization, approval, or order from the FDA under 21 U.S.C. sections 387e(j) or 387j has been sought, and if so the

status, and if not, the reason why a request has not been made (*i.e.*, the information required under Sections 945(c)(9) and (c)(10), to the extent it is different from information given for the Predicate Brand Style). The Attorney General needs to review any difference between the FDA status information applicable to the Variant versus the Predicate Brand Style to which it is related in order to verify that the Brand Style is properly submitted as a Variant, and to evaluate whether this difference necessitates any further review of the Predicate Brand Style's FDA status.

Subdivision (e)(12) requires a design file that contains all visual information needed to show every non-blank side of the packaging for the Variant, or, alternatively, if no design file is available, photographs of every non-blank side of the packaging. This information is necessary for the Attorney General to assess the Variant's packaging for indications that the product has a Characterizing Flavor.

Subdivision (e)(13) requires a written description of images depicted in the design file or photos as described in subdivision (c)(7) of Section 945. These descriptions must include any images on the package that correspond to a flavor and any written descriptors of flavors on the product packaging. This information is necessary for administrative efficiency in processing images to assist the Attorney General's assessment of the Brand Style's packaging for indications that the product has a Characterizing Flavor.

Subdivision (e)(14) requires Applicants to submit any determinations regarding flavor in the Variant made by another government agency, if different from any determinations provided with the Product Form for the related Predicate Brand Style. This information is needed so the Attorney General can assess whether or not the Variant has a Characterizing Flavor.

Subdivision (e)(15) requires Applicants to confirm that several aspects of the Brand Style are unchanged from the Predicate Brand Style: brand name, Sub-Brand name, and Marketing Descriptor; product details based on the tobacco product category to which the Variant belongs; product count per package; volume; weight; length; circumference diameter, or ring gauge; fill type; whether the product contains added nicotine; the type of added nicotine, including tobacco-derived nicotine, synthetic nicotine, nicotinic alkaloid or nicotine analog, or other type of nicotine; a description of the nicotine analog, nicotinic alkaloid or other type of nicotine; and the concentration or strength of nicotine in the product; whether the product contains Cannabis; whether the product contains a capsule; wrapper type; device type; package type; for e-cigarettes and vapes, the device name, whether it contains a lithium-ion battery, and battery capacity; and for e-liquids and heated tobacco products, the name of the device it is intended to be used in. This information is necessary to confirm that the Brand Style is properly submitted for placement on the UTL as a Variant and does not require an independent assessment.

Subdivision (e)(16) allows Applicants to provide additional information or comments regarding the Brand Style that the Applicant considers relevant to the Attorney General's determination as to whether or not the Brand Style is an unflavored tobacco product under Health and Safety Code section 104559.5. This option is necessary to provide the Attorney General with information sufficient to evaluate Applicant's UTL application.

§ 947. Request for Placement on the Unflavored Tobacco List

Section 947 establishes the process, after submitting one or more Product Forms or Variant Forms, that Applicants must complete to request placement of a Brand Style or multiple Brand Styles on the UTL.

Subdivision (a) requires the submission of a UTL application to request placement of a Brand Style on the UTL and specifies that the application may only be completed for a Brand Style after an associated Product Form or Variant Form has been submitted. Requiring submission of the prescribed forms ensures that Applicants provide all the required information and certifications to the Attorney General and provide the Attorney General information sufficient to evaluate whether Brand Styles are eligible and qualified for placement on the UTL.

Subdivisions (b)(1) and (b)(2) require Applicants to identify the Brand Style(s) requested to be placed on the UTL and certify that the Brand Style(s) do not have a Characterizing Flavor. This information is required by Health and Safety Code section 104559.1, subdivision (b)(1).

Subdivisions (b)(3) and (b)(4) require Applicants to confirm certain conditions in the event of litigation arising from enforcement of Health and Safety Code section 104559.1 or regulations adopted under Section 104559.1, including waiver of any sovereign immunity defense and consent to the jurisdiction of the California courts. This is required by Health and Safety Code section 104559.1, subdivision (i).

Subdivision (b)(5) requires Applicants to confirm that a sample of each Brand Style, in the largest packaging unit marketed for sale, has been shipped in accordance with the mailing instructions provided on the UTL application, unless the Brand Style has been submitted as a Variant. This is necessary so that the Attorney General may evaluate the actual product for indications that it has a Characterizing Flavor.

Subdivision (c) requires Applicants to certify under penalty of perjury that the statements in the UTL application and associated Product Form or Variant Form of each Brand Style requested to be placed on the UTL are true. Subdivision (c) further provides for the Attorney General's declination to list, or initiation of removal from the UTL, a Brand Style in the event the Attorney General deems information submitted about the Brand Style on the UTL application, Product Form, or Variant Form to be false. The necessity for a certification under penalty of perjury is to impress upon Applicants the seriousness and importance of submitting accurate information on the application and forms, to attest to the accuracy and completeness of the information submitted, and to deter misrepresentations and submission of false information. The necessity for declination or removal is also to deter misrepresentations and submission of false information, and to keep off the UTL tobacco products that have a Characterizing Flavor or that otherwise are not eligible for placement.

Subdivision (d) requires payment of applicable fees to be made through the payment system on the UTL web portal in order to complete submission of a UTL application. This requirement is necessary to ensure that Attorney General resources are not spent reviewing and processing applications unless the required fees, which are needed to offset the costs associated with operating the UTL, are paid. Subdivision (d) also provides that the Attorney General may permit

exceptions to payment via the payment system on the web portal, on a case-by-case basis. This exception is needed to allow the Attorney General to address unforeseen circumstances.

Subdivision (e) requires for each Brand Style (1) that UTL applications are complete, and (2) that UTL applications are approved by the Attorney General in order for the Brand Style to be placed on the UTL, even if similar Brand Styles are already on the UTL. Subdivision (f) further explains that any Brand Style that has not been approved through a UTL application is deemed a flavored Tobacco Product under Health and Safety section 104559.1, subdivision (g). This is necessary to ensure that Applicants complete all required information so that the Attorney General may receive information sufficient to determine whether or not a Brand Style should be approved for the UTL.

Subdivisions (f) and (g) establish the time frames for the Attorney General's review and response to UTL Applications: applications submitted by the Initial Unflavored Tobacco List Deadline will be considered for inclusion on the initial UTL published, and applications submitted thereafter will receive a response by March 31, 2026, or within 90 days of the submission, whichever is later. Subdivisions (g) and (h) further explain that the Attorney General's response to an application may be approval, denial, or a request for additional information. These dates are necessary to provide Applicants with timelines so that they know when to submit applications ahead of new product launches. The dates are also necessary for the initial UTL publication in order to provide Applicants with the knowledge that their products will be reviewed before the list is published. This is important because once the UTL list is published, any covered product not on the list will be deemed flavored and illegal for sale.

§ 948. Impact of FDA Status on Listing and Removal

Section 948 sets forth public health-based criteria for market access in California to tobacco products that require but have not received authorization, approval, or order from the FDA under 21 U.S.C. Secs. 387e(j) or 387j.

The Attorney General finds that the FDA's premarket tobacco product authorization process is designed to reduce the toll tobacco product use takes on public health by, among other things, incorporating testing for consumer health protection and adherence to good manufacturing practices. Recognizing that the FDA's premarket tobacco authorization process plays a critical role in the protection of public health, the Attorney General finds that tobacco products that are marketed without the requisite authorization and whose manufacturers have failed to comply with the FDA's application deadlines for premarket authorization pose a public health threat to Californians.

In Section 948, the Department identifies the circumstances in which the Attorney General will exercise discretion to exclude a Brand Style from the UTL under Health and Safety Code section 104559.1, subdivision (e) because the Applicant is required to obtain, but has not received, a formal authorization, approval, or order from the FDA under 21 U.S.C. section 387e(j) or 387j.

Subdivision (a) explains that the Attorney General declines to list on the UTL a Brand Style that does not have the required FDA authorization, approval, or order, unless if falls within a listed exception.

Subdivisions (a)(1) through (a)(3) lists three exceptions from UTL ineligibility for a Brand Style that lacks the requisite FDA authorization, approval, or order: (1) a Brand Style that was brought within the regulatory authority of the FDA under the May 10, 2016 Deeming Rule, 81 Federal Register 28973 through 29104, was marketed in the United States as of August 8, 2016, and has a pending application for formal authorization, approval, or order that was submitted to the FDA by FDA's September 9, 2020 deadline; (2) a Brand Style that contains synthetic nicotine, was marketed in the United States as of April 14, 2022, and has a pending application for formal authorization, approval, or order that submitted to the FDA by the FDA's May 14, 2022 deadline; and (3) a Brand Style that meets one of the above two exceptions but no longer has a pending application with the FDA because a negative action on that application has been stayed or rescinded by the FDA, or vacated by a court of competent jurisdiction. The first two exceptions are necessary to promote fairness by including on the UTL unflavored Brand Styles that were already on the market before they fell within the FDA's regulatory authority and subsequently complied with the applicable premarket application deadlines established by the FDA. The third provision is needed to promote fairness and administrative efficiency by avoiding UTL exclusion based on a negative action by the FDA that is under further consideration by the FDA or has been stayed or vacated by a court of competent jurisdiction.

Subdivision (b)(1) provides an exception from ineligibility for the UTL for a Brand Style that does not have FDA authorization, approval, or order, if the Applicant demonstrates 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. Subdivision (b)(1) is needed to provide Applicants the opportunity to demonstrate that a Brand Style does not require premarket authorization and, therefore, has not failed to comply with FDA requirements. This provision is also needed so that Brand Styles are not excluded from the UTL when a rule, guidance, or other formal statement from the FDA that is new or unknown to the Attorney General establishes that the Brand Style does not require authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j.

Subdivision (b)(2) provides an exception from UTL ineligibility for a Brand Style that has been deemed to be within the FDA's regulatory authority, was marketed in the United States as of the date it was deemed or otherwise brought within FDA's regulatory authority, and for which the Manufacturer or Importer of the Brand Style has a pending application for formal authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j that was submitted by the deadline established by the FDA, or has received a negative action that was stayed or rescinded by the FDA or vacated by a court of competent jurisdiction. Subdivision (b)(2) is needed to provide Applicants the opportunity to demonstrate other situations that may arise in which an existing Brand Style is brought within FDA's authority, the Applicant complied with FDA's application deadline for that Brand Style, and the application for the Brand Style is accepted by FDA and remains pending, or, if the application received a negative action, that such negative action is stayed or rescinded by the FDA or vacated by a court of competent jurisdiction.

Subdivision (c) provides that a Brand Style for which a UTL application has been submitted with a Variant Form will not be excluded from the UTL for lacking the required FDA authorization,

approval, or order under 21 U.S.C. sections 387e(j) or 387j. This exception for Variants is needed because the consumable product of a Predicate Brand Style and its associated Variant must be the same under subdivision (a) of Section 946, and a Manufacturer or Importer's compliance with the FDA's deadlines for a Predicate Brand Style is sufficient indicia that the Manufacturer 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.

§ 949. Requests for Additional Information

Section 949 establishes a procedure for the Attorney General to request additional information about a Brand Style. These provisions are needed so that the Attorney General may seek and receive information necessary to determining whether to a Brand Style qualifies for inclusion on the UTL.

Subdivision (a) allows the Attorney General to request additional information if needed for the Attorney General to evaluate whether Applicant's Brand Style lacks a Characterizing Flavor. This provision is needed because, after reviewing the information requested by the UTL application and accompanying Product Form or Variant Form, the Attorney General may require additional information to evaluate whether the Brand Style has a Characterizing Flavor or is otherwise ineligible for inclusion on the UTL. Subdivision (a) requires Applicants to provide the requested information within thirty (30) days and subjects the Brand Style to exclusion or removal from the UTL if they fail to meet the deadline, or fail to provide the requested information. Applicants may include in their response any other information that it deems relevant to substantiate its contention that the Brand Style lacks a Characterizing Flavor. The Attorney General finds that 30 days is a reasonable amount of time for Applicants to gather and provide the additional information requested. The time limit and the provision allowing the Attorney General to remove a Brand Style from the UTL or decline to list a Brand Style on the UTL if the Manufacturer or Importer fails to respond to a request is needed for administrative efficiency.

Subdivision (b) allows the Attorney General to request additional information regarding a Brand Style's packaging, marketing, and status with the FDA. This provision is needed because, after reviewing the information requested by the UTL application and accompanying Product Form or Variant Form, the Attorney General may require additional information to evaluate whether the Brand Style has a Characterizing Flavor or is otherwise ineligible for inclusion on the UTL. Applicants are required to provide such information and documentation within fifteen (15) days of a request from the Attorney General, and failure to provide the requested information or failure to do so timely subjects the Brand Style to exclusion or removal from the UTL. Subdivision (b)(3)(A) of Health and Safety Code section 104559.1 authorizes the Attorney General to request information and documentation regarding tobacco product status, packaging, or marketing of a Brand Style to evaluate a product for placement on the UTL, and subdivision (b) establishes the procedure for requests for such information not already provided in a Product Form or Variant Form. The time limit and the provision allowing the Attorney General to decline to list a Brand Style or remove a Brand Style from the UTL if the Applicant fails to respond to a request, is needed for administrative efficiency. The time limit for responding to a request for product status, packaging, or marketing under subdivision (b) is less than the time limit to

substantiate that Brand Style lacks a Characterizing Flavor under subdivision (a) because the Attorney General expects that it will require less Applicant time to respond to a request under subdivision (b).

Subdivisions (c)(1) through (c)(3) identify the possible responses that Applicants may receive after they provide additional information requested by the Attorney General. No later than 30 days after receiving the Applicant's timely response, the Attorney General will: approve the Brand Style to be listed or remain on the UTL; request additional information to substantiate whether the Brand Style lacks a Characterizing Flavor; request additional information and documentation regarding a Brand Style's packaging, marketing, or status with the FDA; or provide notice that the Attorney General declines to list the Brand Style on the UTL or is initiating removal of the Brand Style from the UTL. This information apprises Applicants of further actions that may be taken on the Brand Style or that may be needed on their part. The Attorney General finds that 30 days is a reasonable amount of time to review the additional information provided.

§ 950. List Removal

Section 950 lists the grounds and establishes a procedure for removing Brand Styles from the UTL.

Subdivision (a) provides that the Attorney General shall initiate removal of a Brand Style from the UTL if the Attorney General determines the Brand Style has a Characterizing Flavor. This provision effectuates subdivision (f)(1) of Health and Safety Code section 104559.1, which requires the Attorney General to remove a Brand Style from the UTL if the Attorney General determines the Brand Style imparts a Characterizing Flavor.

Subdivision (b) provides that the Attorney General will initiate removal from the UTL any Brand Style that is ineligible for listing under Section 948. Subdivision (b) effectuates subdivision (e) of Health and Safety Code section 104559.1, which provides the Attorney General discretion to decline to include on the UTL any Brand Style that is "required to obtain and has not received a formal authority, approval, or order" under 21 U.S.C. section 387e(j) or 387j.

Subdivisions (c) through (f) establish the procedure for removal of a Brand Style. Subdivision (c) requires the Attorney General to provide a notice of initiation of removal identifying the basis for the removal sixty (60) days prior to the removal, or, for removals based on Section 951, notifying Applicant that the Brand Style will be removed on or after June 30 of that year for failure to renew UTL placement. The Attorney General shall notify Applicant of any modifications to the notice of initiation of removal if the basis for the removal changes.

Subdivision (d) requires that thirty (30) days later, the Attorney General must provide a final notice of removal that informs the Manufacturer or Importer that the Brand Style will be removed in thirty (30) days, or for removals under Section 951, on or after June 30. On the same day a final notice of removal is provided to Applicant, a public notice will be posted on the Attorney General's website.

Subdivision (e) requires the Attorney General to post a public notice to the website when a Brand Style is removed from the UTL.

Subdivision (f) allows Manufacturers and Importers to provide additional materials to the Attorney General to avoid removal.

The removal procedure provides public notice of the final notice of removal, certain modified determinations by the Attorney General regarding the removal, and actual removals, and also provides Manufacturers and Importers the opportunity to provide additional materials to the Attorney General that may avoid removal. The public notices are needed to apprise enforcement officials and tobacco product retailers, wholesalers, distributors, and delivery-sellers of impending and actual removals, so that the retailers, wholesalers, distributors, and delivery-sellers may stay compliant with the restrictions on sales of products not appearing on the UTL. The time limits identified in subdivisions (c) through (f) are needed for administrative efficiency and to comply with the removal requirements of subdivision (f) of Health and Safety Code section 104559.1.

§ 951. Renewals

Section 951 establishes requirements to renew a Brand Style's placement on the UTL.

Subdivision (a) requires renewal applications to be made between April 1 and April 15 of each year and provides that the Attorney General will initiate removal of Brand Styles in the absence of a timely renewal. The time limits are necessary to provide the Attorney General with sufficient time to determine which Brand Styles have not been renewed. The consequence for failure to renew is necessary to ensure that Brand Styles only remain on the list if the Applicant for the Brand Style has certified, through a renewal application, that such Brand Styles are unchanged from the approved UTL application.

Subdivision (b) establishes the procedure to submit a renewal application and requires that Applicants certify under penalty of perjury that they have reviewed the most recent Product or Variant Form for the Brand Style and that all information remains accurate. This certification is required to ensure that the Brand Style remains eligible and qualified for placement on the UTL.

Subdivision (c) requires the annual renewal fee to be made through the online payment system on the Attorney General's UTL web portal in order to complete a renewal application. This requirement is necessary to ensure that the Attorney General collects the statutory annual renewal fee (Health & Saf. Code, § 104559.1, subd. (k)(1)), which is used to offset the costs associated with operating the UTL. Subdivision (c) also provides that the Attorney General may permit exceptions to payment via the payment system on the web portal, on a case-by-case basis. This exception is needed to allow the Attorney General to address unforeseen circumstances.

§ 952. Updates

Section 952 requires Applicants to provide updated information for Brand Styles that the Attorney General has already approved for placement on the UTL.

Subdivision (a) requires submission of a new UTL Application for most changes regarding a Brand Style listed on the UTL. This is necessary to ensure that the Attorney General can review any change to a Brand Style that may impact its status on the UTL.

Subdivisions (b)(1) through (b)(4) carve out exceptions where an update, rather than a new application, is required: changes to the trademark holder; FDA status and receipt of new documents from the FDA; and receipt of additional flavor determinations from other jurisdictions. Requiring such supplemental information is necessary to provide the Attorney General information to evaluate whether the Brand Style remains eligible and qualified for placement on the UTL. Because a change in the trademark holder does not require substantive review by the Attorney General, only an update through the web portal, rather than a new application, is required. Because status changes from FDA and additional flavor determinations from government agencies will generally require limited review by the Department and are the result of agency actions outside the control of an Applicant, the Department finds that submission of an updated Application at no additional cost to Applicant is appropriate. These updates must be provided within 15 days. The Attorney General finds that 15 days is a reasonable amount of time because this is simple information that can be provided quickly.

Subdivision (c) allows the Attorney General to remove a Brand Style from the UTL if changes to that Brand Style are not reported. This consequence is necessary to prevent Brand Styles that no longer qualify for placement on the UTL from remaining on the list, and to provide the Attorney General with information to evaluate whether a Brand Style continues to meet requirements to remain on the UTL.

§ 953. Designation of Confidential Information

Section 953 identifies non-exhaustive categories of information and documentation that, when submitted as part of a request for placement on the UTL, the Attorney General considers confidential and not subject to disclosure under the California Public Records Act. These provisions are needed to protect the confidential and proprietary information provided by Applicants.

Subdivision (a) explains that the FDA-related information submitted by Applicants, if designated non-public, is considered by the Attorney General to be confidential and corporate proprietary information under subdivision (b)(3)(B) of Health and Safety Code section 104559.1. Subdivisions (a)(1) through (a)(7) explain that the publicly disclosable FDA status designations, based on Applicant responses on a Product Form or Variant Form, that will not be considered confidential and proprietary are: “FDA authorization, approval, or order received,” “Under Review by FDA,” “Negative action on application stayed or rescinded by FDA,” “Negative action on application vacated by court,” “Provisional Substantial Equivalence Product Removed From Review under 21 U.S.C. section 387j(a)(2)(B),” “FDA authorization, approval, or order not sought,” and “FDA authorization, approval, or order denied.” These FDA designations regarding the marketing status of products are disclosable because they describe whether authorization, order, or approval under 21 U.S.C. sections 387e(j) or 387j has been sought and the status of any such request for authorization, approval, or order under subdivision (b)(1)(B) of Health and Safety Code section 104559.1. By contrast, the remaining information provided by Applicants under subdivisions (c)(9) and (c)(10) of Section 945, subdivision (e)(11) of Section

946, and subdivisions (b)(2) or (b)(3) of Section 952 is additional information and documentation regarding the Brand Style's FDA status that may disclose information regarding business sensitive or trade secret product designs or administrative processes; therefore, if designated non-public by the Applicant, this additional information and documentation is protected from disclosure under subdivision (b)(3)(B) of Health and Safety Code section 104559.1 to facilitate full and accurate reporting to the Attorney General.

Subdivision (b) provides that, if designated by Applicant as non-public, product design files submitted under subdivision (c)(7) of Section 945 and subdivision (e)(12) of Section 946 are considered confidential under of Health and Safety Code section 104559.1, subdivision (b)(3)(B). Product design files qualify as packaging and marketing materials under subdivision (b)(3)(B) of Health and Safety Code section 104559.1 because they show the visual layout and structure of the product package, including folding lines and pre-assembly structure, and may also include non-public, business sensitive or trade secret information (e.g., exact print details that could, if public, facilitate accurate contraband duplication of packaging). Subdivision (b) provides that, if designated by Applicant as non-public, information and documentation regarding a Brand Style's packaging, marketing, and status with the FDA provided in response to a request by the Attorney General under subdivision (b) of Section 949 is considered confidential under of Health and Safety Code section 104559.1, subdivision (b)(3)(B). Including this statutory rule in the regulations is necessary for clarity so that the confidentiality rules arising from Health and Safety Code section 104559.1 are in one place.

Subdivision (c) provides that additional information and documentation submitted by Applicants under subdivision (f) of Section 950 that relates a decision to remove a Brand Style from the UTL based on its Characterizing Flavor or FDA status and is considered confidential and proprietary information, as required under Health and Safety Code section 104559.1, subdivision (f)(2)(D). Including this statutory rule in the regulations is necessary for clarity so that the confidentiality rules arising from Health and Safety Code section 104559.1 are in one place.

Subdivisions (d)(1) through (d)(2) explain that information provided in a Product Form or Variant Form and responses to requests for additional information under subdivision (a) of Section 949 regarding a Brand Style's lack of Characterizing Flavor will be considered confidential and proprietary information, as required under Health and Safety Code section 104559.1, subdivision (b)(2)(B). Including this statutory rule in the regulations is necessary for clarity so that the confidentiality rules arising from Health and Safety Code section 104559.1 are in one place.

Subdivision (e) provides that the Attorney General may disclose confidential information to third-party consultants designated by the Attorney General that agree in writing to maintain the confidentiality of the information. This is necessary so that the Attorney General may engage consultants to assist with analyzing the technical information and documentation provided by Applicants.

§ 954. Application Fees

Section 954 sets the fees required for submission of each Brand Style to the UTL. Subdivision (k)(1) of Health and Safety Code section 104559.1 authorizes the Attorney General to set a fee

up to $1,000 per Brand Style for each initial submission, not to exceed the reasonable costs of processing submissions and operating the UTL, and up to $1,000 per Brand Style for each annual renewal, not to exceed the reasonable costs of maintaining the UTL. The Department does not at this time anticipate that the full fees authorized by the statute will be required to operate and maintain the UTL.

Subdivision (a) requires an initial application fee of $300 for each Brand Style submitted for placement on the UTL, other than Variants. Subdivision (b) requires a fee of $150 for each Variant, as defined by Section 946, submitted for placement on the UTL. Subdivision (c) requires an annual renewal fee of $150 for all Brand Styles, whether originally submitted for placement on the UTL with a Product Form or Variant Form. The fee provisions in subdivisions (a) through (c) are needed to notify Applicants of the specific cost for submitting a Brand Style to the UTL, either for initial or renewed placement on the list. The fees set forth in subdivisions (a) through (c) are based on the Department's estimate of the number of Brand Styles that will be submitted for inclusion on the initial publication of the UTL and in subsequent years, and the Attorney General's costs associated with operating and maintaining the UTL based on the estimated number of submitted Brand Styles, as described in STD 399 Attachment A, Fiscal Impact Statement, Section B – Fiscal Effect on State Government.

Subdivision (d) states that all fees shall apply to the current fiscal year ending June 30 and shall not be prorated, as provided by Health and Safety Code section 104559.1, subdivision (k)(1). Including this statutory rule in the regulations is necessary for clarity so that all fee information is in one place.

Subdivision (e) requires fees to be paid in full before a request for placement of a Brand Style on the UTL is considered by the Attorney General, and that payment of fees for inclusion of a Brand Style on the initial UTL, to be published on or before December 31, 2025, must be received by the Initial Unflavored Tobacco List Deadline. This requirement is necessary to ensure that Attorney General resources are not spent reviewing and processing applications from Applicants before they pay the required fees. Subdivision (e) also sets a deadline of April 15 for payment of renewal fees so that the Attorney General has sufficient time to determine which Brand Styles have not been renewed and provide public notice of the non-renewed Brand Styles that will be removed from the UTL.

§ 955. Penalty Citations

Section 955 establishes the procedures for assessing civil penalties under Health and Safety Code section 104559.1, subdivision (o)(3) against distributors, wholesalers, and delivery sellers (hereinafter "affected sellers") that sell any Brand Style not appearing on the UTL or any Tobacco Product Flavor Enhancer to any retailer, wholesaler, or other person in California.

Health and Safety Code section 104559.1, subdivision (q), allows the Attorney General to adopt an administrative process for the imposition of civil penalties. Section 955, subdivision (a) provides that the Attorney General may either bring a civil action in the name of the People of the State of California or serve a written citation that states the basis of the violation and penalty amount by personal service or certified mail to assess penalties under Health and Safety Code section 104559.1, subdivision (o)(3). The provisions of subdivision (a) are needed to ensure

alleged violators are apprised of the pendency and nature of the proceedings and the penalties sought. The Attorney General has elected to create an administrative process because it is less burdensome and costly for all parties. However, a civil action may be appropriate in some cases.

Subdivision (b) requires the Attorney General to consider all relevant circumstances when assessing the amount of the penalty. Subdivisions (b)(1) through (b)(5) identify non-exclusive factors that the Attorney General will consider, including: the nature and severity of the violation, history of similar violations, good or bad faith exhibited by the cited person or entity, the extent to which the cited person has cooperated with the Attorney General, and the size and resources of the cited person or entity. These non-exhaustive factors, modeled after the Attorney General's administrative fine assessments for the Controlled Chemical Substance Program (see Cal. Code Regs., tit. 11, § 810.4), are taken into account to help ensure that penalty assessments are reasonable and fair.

Subdivision (c) provides that service of a citation is deemed complete upon personal service or receipt by certified mail. Establishing the completion of service is needed to promote administrative efficiency and to ensure the cited individual or entity is provided notice of the proceedings.

Subdivision (d) requires payment of penalties within thirty (30) days of service of the citation, unless a timely appeal has been filed. A time limit is necessary to ensure that civil penalty payments are paid. The Attorney General may extend this deadline in writing.

§ 956. Appeals

Section 956 establishes the procedures for affected sellers to appeal citations and the procedures for administrative hearings on those appeals. This section is modeled after the Attorney General's regulations related to the administrative enforcement of the supervision of trustees and fundraisers for Charitable Purposes Act. **(**See Cal. Code Regs. tit. 11, § 336.)

Subdivision (a) requires an appeal of a citation issued under Section 955 to be submitted to the Attorney General within thirty (30) days, or the right to appeal is waived and the citation becomes a final order. A time limit for appeal is needed for administrative efficiency and to ensure that civil penalty payments are paid, while also providing affected sellers an opportunity to present objections. Subdivision (a) further requires that an appeal must include the name of the cited person or entity, contact information for the appellant, and the basis for the appeal. This information is necessary to ensure that communications regarding the appeal process are properly directed to the appellant and to inform the Attorney General of the affected seller's basis for objection to the citation.

Subdivision (b) establishes the procedure by which the appellant will receive notice of the appeal hearing date, time, and place, and deems the appellant's failure to appear at the hearing to be a withdrawal of the appeal, which in turn will render the citation a final order. These provisions are required to ensure that affected sellers are provided an opportunity to make objections to the citation, for administrative efficiency, and to allow finality of a citation in the event the affected seller fails to proceed in their appeal.

Subdivision (c) requires all hearings to be conducted by an administrative hearing officer designated by the Attorney General and requires that the hearing officer shall not have participated in the underlying citation. Provision of an administrative hearing officer allows for review of an affected seller's citation and objections to that citation. The prohibition against hearing officers that have participated in the decision concerning the administrative action that is the subject of the hearing or are otherwise subject to the disqualification provisions of sections 11425.30 and 11425.40 of the Government Code is needed to avoid bias and prejudice in administrative adjudications.

Subdivision (d) requires all hearings to be conducted in accordance with the procedures set out in Chapter 5 (commencing with section 11500) of Part 1 of Division 3 of Title 2 of the Government Code. Establishing procedures for the administrative hearing on citation appeals is needed to govern the conduct of all participants and to ensure fairness and adherence to legal standards.

§ 957. Review of Appeal Hearing Officer's Proposed Decision

Section 957 establishes procedures for review of a hearing officer's proposed decision on an appeal.

Subdivision (a) requires that within fifteen (15) days after service of the hearing officer's proposed decision on an appeal, any party to the administrative action may file and serve on all parties a brief seeking the Attorney General's review of the proposed decision. This subdivision further provides that failure to meet this deadline waives the party's right to review. These procedures are needed to allow the parties an opportunity to make objections to the hearing officer's proposed decision, and the time limits are required for administrative efficiency and to provide closure of the administrative action where parties have failed to act.

Subdivision (b)(1) requires that an opposition brief to a request for review of a hearing officer's proposed decision mut be filed and served withing fifteen (15) days of the brief requesting review. A time limit for the submission of an opposition brief is needed for administrative efficiency and to promote fairness by providing an opportunity to respond to points made in the request for review.

Subdivisions (b)(2)(A) through (b)(2)(C) establish the permissible topics for briefing on a request for review of a hearing officer's proposed decision. A list of the topics to be covered by the briefing regarding a review request is needed to provide the Attorney General with information sufficient to evaluate the review request and the proposed decision.

Subdivisions (c)(1) through (c)(4) inform affected sellers of the possible actions that the Attorney General may take once briefing of the request for review of the hearing officer's proposed decision is complete. These actions include: adopt the proposed decision, reduce or mitigate the proposed decision, make technical or non-substantive changes to the proposed decision, or decline to adopt the proposed decision and either decide the case upon the administrative record or refer the matter back to the hearing officer to take additional evidence. This provision is necessary to establish the scope of actions that can be taken on a review request.

Subdivision (d) provides that the hearing officer's proposed decision is deemed adopted by the Attorney General 100 days after service of the proposed decision, unless the Attorney General notifies the parties that it is not adopted or is modified, or the Attorney General refers the matter to the hearing officer to take additional evidence. This time limit is necessary for administrative efficiency.

Subdivision (e) allows the Attorney General to extend the deadlines for briefing on review of the hearing officer's proposed decision. The necessity of this subdivision is to allow the Attorney General to accommodate circumstances unforeseen by these regulations.

RELIED ON DOCUMENTS

List each technical, theoretical, and empirical study, report, or similar document, if any, upon which the Department relied.

Food & Drug Administration, "Market and Distribute a Tobacco Product," <https://www.fda.gov/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product> (as of July 9, 2025).

U.S. Food and Drug Administration, "Tobacco Product Marketing Orders," <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders> (as of July 9, 2025).

U.S. Food and Drug Administration, "Requirements for Products Made with Non-Tobacco Nicotine Take Effect April 14," <https://www.fda.gov/tobacco-products/ctp-newsroom/requirements-products-made-non-tobacco-nicotine-take-effect-april-14#:~:text=Further%2C%20manufacturers%20of%20NTN%20products,%2C%20May%2013%2C%202022).> (as of July 9, 2025).

U.S. Food and Drug Administration, "Regulation and Enforcement of Non-Tobacco Nicotine (NTN) Products," <https://www.fda.gov/tobacco-products/products-ingredients-components/regulation-and-enforcement-non-tobacco-nicotine-ntn-products#:~:text=In%20response%20to%20the%20increase,any%20source%2C%20including%20synthetic%20nicotine.> (as of July 9, 2025).

U.S. Food and Drug Administration, "Tobacco Product Marketing Orders," < https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders#:~:text=A%20pre%2Dexisting%20tobacco%20product%20is%20any%20tobacco%20product%20(including,on%E2%80%9D%20or%20before%20that%20date.> (as of July 9, 2025).

U.S. Food and Drug Administration, "Pre-Existing Tobacco Products," < https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/pre-existing-tobacco-products> (as of July 9, 2025).

AUTHORITY AND REFERENCE CITATIONS

Authority: Section 104559.1, Health and Safety Code.
Reference: Sections 104559.1 and 104559.5, Health and Safety Code; Sections 22971 and 26001, Business and Professions Code; Section 30019, Revenue and Tax Code; 21 U.S.C. Sections 387a, 387e, 387j.

DISCLOSURES REGARDING THE PROPOSED ACTION

The Department has made the following initial determinations:

Mandate on local agencies or school districts: None.

Cost or savings to any state agency: The fees collected will be used to offset the costs incurred by the Attorney General for processing the submissions and operating and maintaining the UTL.

Cost to any local agency or school district which must be reimbursed in accordance with Government Code sections 17500 through 17630: None.

Other non-discretionary costs or savings imposed on local agencies: None.

Cost or savings in federal funding to the state: None.