CALIFORNIA DEPARTMENT OF JUSTICE

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

TEXT OF PROPOSED REGULATIONS

Chapter 11. Unflavored Tobacco List

Article 1. General

§ 942. Definitions

For the purposes of this chapter, the following definitions apply:

(a) "Applicant" means a Manufacturer or Importer.

(b) "Attorney General" means the Attorney General of the State of California or any employee of the Attorney General acting under the authority of the Attorney General.

(c) "Brand Style" has the same meaning as set forth in Health and Safety Code section 104559.1, subdivision (s)(1).

(d) "Cannabis" has the same meaning as set forth in Business and Professions Code section 26001.

(e) "Carton or Roll" means 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.

~~(e)~~(f) "Certifying User" means a User that is also authorized to submit Unflavored Tobacco List applications, renewal applications, updates, and otherwise make binding certifications on behalf of an Applicant.

~~(f)~~(g) "Characterizing Flavor" has the same meaning as set forth in Health and Safety Code section 104559.1, subdivision (s)(2). A Brand Style "lacks a Characterizing Flavor" if it lacks any Constituent that imparts a Characterizing Flavor.

~~(g)~~(h) "Constituent" has the same meaning as set forth in Health and Safety Code section 104559.5, subdivision (a)(2).

~~(h)~~(i) "FDA" means the United States Food and Drug Administration.

~~(i)~~(j) "Importer" means any purchaser for resale in the United States of Tobacco Products manufactured outside of the United States for the purpose of making a first sale or distribution within the United States.

~~(j)~~(k) “Manufacturer” means any person who manufactures, fabricates, assembles, processes, or labels a finished Tobacco Product and any other person licensed as a manufacturer by the California Department of Tax and Fee Administration under Business and Professions Code sections 22979 or 22979.21.

~~(k)~~(l) “Marketing Descriptor” means a descriptor, such as a color or image description, that distinguishes Brand Styles within a brand or Sub-Brand.

~~(l)~~(m) “Multipack” is a Brand Style that includes either (1) any Predicate Brand Style(s) and any device(s), (2) multiple different Predicate Brand Styles, or (3) multiple packages of the same Predicate Brand Style.

~~(m)~~(n) “Predicate Brand Style” means a Brand Style for which an Applicant has previously completed a product form or variant form.

~~(n)~~(o) “Sub-Brand” means a secondary brand that, in addition to the brand, identifies the Brand Style and is used across a Product line.

~~(o)~~(p) “Tobacco Product” or “Product” has the same meaning as set forth for “Tobacco product” in Health and Safety Code section 104559.1, subdivision (s)(3).

~~(p)~~(q) “Unflavored Tobacco List” or “UTL” means the Unflavored Tobacco List described in Health and Safety Code section 104559.1, subdivision (a).

~~(q)~~(r) “User” means an agent authorized by an Applicant to view account information and draft and submit product forms and variant forms, as described in Sections 945 and 946.

~~(r)~~(s) “Variant” means 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. “Variant” does not include any Brand Style with a packaging difference that imparts flavor.

NOTE: Authority cited: 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 Taxation Code.

Article 2. Applications, List Removal, and Renewals

§ 943. Applicant Information and Account Creation

(a) Applications for placement on the UTL shall be submitted through the Attorney General's UTL web portal at https://utl.doj.ca.gov.

(b) A User must create or access an applicant account and a user account to use the UTL web portal. Accounts must be created online at https://utl.doj.ca.gov.

(c) Users shall agree to the following conditions of use:

(1) 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 via email at: UTLinbox@doj.ca.gov.

(2) All submissions made via the UTL web portal will be electronically dated.

(d) To create an applicant account, User shall provide all of the following:

(1) Applicant's name;

(2) Applicant's California Department of Tax and Fee Administration license number, if any;

(3) Applicant's federal employer identification number, if any;

(4) Applicant's Alcohol and Tobacco Tax and Trade Bureau Permit Number, if any;

(5) Applicant's mailing address;

(6) Email address where Applicant will receive communications related to web portal applications submitted by its Certifying Users;

(7) Address of Applicant's principal place of business;

(8) Website address of Applicant, if any;

(9) The name, physical address, telephone number, and email address of Applicant's registered agent for service of process;

(10) Whether the Applicant is a Manufacturer or Importer; and

(11) A letter from Applicant on Applicant's official letterhead that is signed by someone authorized to bind Applicant and that authorizes User to create an applicant account. An Applicant may authorize other Users in this letter, but for each User, Applicant must identify whether User is a Certifying User or other User. Applicant must authorize at least one Certifying User, which may be the User creating the applicant account. For each User the letter authorizes, the letter must provide an email address for the User. Certifying Users may

submit additional letters complying with all of these requirements to authorize, remove, or change the status of a User.

(e) Each User (except the User creating the applicant account) authorized by the letter described in subdivision (d) will receive an email to create a user account at the email address provided in the signed letter described in subdivision (d)(11), except as otherwise provided in subdivision (g). Such User, including the initial User that creates the applicant account, must create an individual user account and, to access the associated applicant account, will be required to provide the User's:

(1) Email address;

(2) First and last name;

(3) Title;

(4) Phone number.

(f) If there is any change to the applicant account information listed in subdivision (d), a Certifying User must update that information no later than fifteen (15) days after the change.

(g) A User may be authorized for multiple Applicants. Even if they are authorized for multiple Applicants, a User who has not yet created a user account will only receive one email to create a user account. Once the user account has been created, the User will be given access to the accounts of all Applicants that have listed the User via an authorization letter. A User may be assigned as a Certifying User for multiple Applicants, or as a User for multiple accounts. However, the same User email address cannot be assigned as a Certifying User for one Applicant and a User for another Applicant.

(h) The Attorney General shall deny account requests that do not comply with the requirements of this section or that are false.

NOTE: Authority cited: Section 104559.1, Health and Safety Code. Reference: Section 104559.1, Health and Safety Code.

§ 944. Service Information and Time Limits

(a) All communications described in Sections 943 through 952 of this chapter shall be made electronically. Time limits described in those sections that are triggered by a communication commence on the day that communication is sent to an Applicant at the email address

specified in an applicant account on the Attorney General's UTL web portal, or to the Attorney General at UTLinbox@doj.ca.gov. When the last day to perform or complete any act provided for in this chapter falls on Saturday, Sunday, or state holiday set forth in Government Code section 6700, the time computation excludes that day and includes the next business day. Business days are all days except Saturdays, Sundays, and any state holiday set forth in Government Code section 6700.

(b) The Attorney General shall extend an Applicant's time limits identified in Sections 943 through 954 for up to 60 days, excluding statutorily-imposed time limits, upon a showing of good cause that outweighs the operational needs of the Attorney General. Any granted extension will be for a duration consistent with the basis of the good cause shown. Multiple extensions may be granted for good cause. Good cause requires a satisfactory showing that the Applicant exercised reasonable diligence and a substantial reason for the extension. For example, good cause may be found when the Applicant requires additional time to collect or analyze new or complex information. Examples of operational needs that combined or individually may outweigh an Applicant's good cause include the need to efficiently allocate staff and resources to manage a large volume of work, the need to adhere to legally mandated or public-facing deadlines, and the need to maintain the UTL with products that meet the statutory requirements.

(c) The Attorney General shall extend time limits on the Attorney General, excluding statutorily imposed time limits and the 60-day notice of intent to remove a Brand Style from the UTL, provided in Section 950, subdivision (c), where good cause exists and for such time as is consistent with the basis of good cause shown. Multiple extensions may be granted for good cause, but the total time will not be extended for longer than 90 days without agreement from the affected Applicant. For example, good cause may be found where the Attorney General requires additional time to analyze new or complex information or to do independent testing of Brand Styles.

NOTE: Authority cited: Section 104559.1, Health and Safety Code. Reference: Section 104559.1, Health and Safety Code.

§ 945. Submission of product form

(a) A product form or variant form, as described in Section 946, must be completed and submitted to the Attorney General for a Brand Style in order to apply for placement of that Brand Style on the UTL. A Brand Style will not be considered for placement on the UTL unless and until a UTL application is submitted as outlined in Section 947; a product form or variant form alone is insufficient. A separate product form or variant form is required for each Brand Style, ~~except for a carton or roll of the Brand Style if the following conditions have been met~~with two exceptions:

~~(1) A carton or roll means 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.~~

~~(2) The carton or roll is identified on a product form or variant form.~~

~~(3)~~(1) ~~All~~ 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 ~~must be~~is completed for the ~~c~~Carton or ~~r~~Roll, including submission of a design file or photographs as described in subdivision (c)(7).

(2) A separate product or variant form is not required for 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. Examples of such changes include 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.

(b) Product forms shall be completed and submitted through the Attorney General's UTL web portal. Upon a showing of good cause that outweighs the operational needs of the Attorney General, the Attorney General shall permit exceptions from use of the web portal for product forms and/or variant forms. For example, good cause may be found when the Applicant demonstrates that they lack access to the web portal due to lack of necessary technology or internet connectivity. Examples of operational needs that combined or individually may outweigh an Applicant's good cause include strains on staff resources that divert resources

from more critical responsibilities and difficulties integrating data from outside of the web portal.

(c) To complete a product form for a Brand Style, the following information must be provided:

(1) Brand name; whether or not it has a Sub-Brand name, and if so, the Sub-Brand name; and any Marketing Descriptor;

(2) Universal product code for the Brand Style and for any €Carton or ǂRoll of that Brand Style, and manufacturing stock keeping unit number for the Brand Style and for any €Carton or ǂRoll of that Brand Style if there is no universal product code;

(3) Name of the holder of the trademark on the Sub-Brand name, or, if not applicable, then the holder of the trademark on the brand name, if applicable;

(4) The Tobacco Product category ("Cigarettes"; "Heated Tobacco Products"; "Cigars" (including little cigars)); "E-Cigarettes, Vapes, and E-Liquids" (including electronic pipes and electronic hookahs); "Pipe Tobacco Filler" (exempting looseleaf tobacco, pursuant to Health and Safety Code, section 104559.1, subdivision (s)(3)); "Roll-your-own Tobacco Filler"; "Smokeless Tobacco Products" (including chewing tobacco and snuff); "Nicotine Pouch"; or "Other Tobacco Products") and subcategory:

(A) If the Tobacco Product category is "Cigarettes," specification of whether the Product is combusted-filtered, combusted-non-filtered, or other.

(B) If the Tobacco Product category is "Cigars," specification of whether the Product is sheet- or leaf-wrapped, and whether the Brand Style is filtered or unfiltered.

(C) If the Tobacco Product category is "E-Cigarettes, Vapes, and E-Liquids," specification of whether the Product is E-Cigarette/Vape or E-Liquid. A Product is an E-Liquid if the e-liquid and the device are separable with ordinary use; otherwise, it is an E-Cigarette/Vape. If the Product is an E-Liquid, further specification of whether it is closed or open is required. The E-liquid is "closed" if the liquid is not accessed by the consumer under normal use (such as with a pod), and otherwise is "open."

(D) If the Tobacco Product category is "Smokeless Tobacco Products," specification of whether the Product is loose moist snuff, portioned moist snuff, loose snus, portioned snus, loose dry snuff, dissolvable, loose chewing tobacco, or portioned chewing tobacco.

(E) If the Tobacco Product category is "Other Tobacco Products," a brief description of the Tobacco Product type.

(5) The unit of the Product, as described on the package. The unit may be left blank if already captured by the Tobacco Product category or subcategory type.

(6) Product details ~~specified~~identified below when they apply to the Product as specified by the product form in the UTL web portal. When Product details are left blank even though they apply to the Product, the form shall be deemed incomplete and will not be accepted.

(A) Product count per package;

(B) Volume of the Product (e.g., an e-cigarette may be measured in milliliters or puffs);

(C) Weight of the Product;

(D) Length;

(E) Circumference, diameter, or ring gauge;

(F) Fill type;

(G) 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;

(H) Whether the Product contains added Cannabis;

(I) Whether the Product contains a capsule;

(J) Wrapper type;

(K) Device type;

(L) Package type;

(M) If the Product is an e-cigarette or vape, the device name, whether the device contains a lithium-ion battery, and the battery's capacity;

(N) If the Product is an e-liquid or heated tobacco product, the name of the device it is intended to be used in.

(7) Design file for the Brand Style. The design file must contain all visual information needed to render or show every side of the packaging for the Brand Style that is not blank. If there is no design file available, photos may be provided of every side of the packaging for the Brand Style that is not blank. The design file or photos must include such file(s) or photo(s) for any ~~c~~Carton or ~~r~~Roll of the Brand Style.

~~(8) Written description of images depicted in the design file or photos provided under subdivision (c)(7). There must be a description provided of any images on the package that~~

~~correspond to a flavor and a list of any written descriptors of flavors on the Product packaging.~~

(~~9~~8) Whether the Brand Style has received a formal authorization, approval, or order from the FDA under 21 U.S.C. sections 387e(j) or 387j. Additionally, the following information shall be provided:

(A) If formal authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j has been received for the Brand Style:

i. Identification of all pathways under 21 U.S.C. sections 387e(j) or 387j (Premarket Tobacco Product Form, Substantial Equivalence Report, Exemption from Substantial Equivalence Requests) for marketing the Brand Style for which the FDA provided authorization, approval, or order;

ii. Identification of the date on which the FDA issued the authorization, approval, or order for the Brand Style under 21 U.S.C. sections 387e(j) or 387j; and

iii. Documentation from the FDA establishing that the Brand Style received the required authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j, including any Marketing Granted Order, Substantial Equivalence Order, and Exempt from Substantial Equivalence Order.

(B) If formal authorization, approval, or order has not been received under 21 U.S.C. sections 387e(j) or 387j for the Brand Style, whether any such authorization, approval, or order has been sought for the Brand Style.

i. If formal authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j has been sought for the Brand Style, the following information about the submission to the FDA shall be provided:

I. All pathways under 21 U.S.C. sections 387e(j) or 387j (Premarket Tobacco Product Form, Substantial Equivalence Report, Exemption from Substantial Equivalence Requests) for which authorization, approval, or order for the Brand Style has been sought.

II. For Brand Styles containing nicotine that is not derived from tobacco, whether the Brand Style was commercially marketed in the United States as of April 14, 2022.

III. 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 under subdivision (c)(4) of this Section, whether the Brand Style was commercially marketed in the United States as of August 8, 2016.

IV. The date of 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.

V. For each request submitted for authorization, approval, or order for the Brand Style under 21 U.S.C. sections 387e(j) or 387j, whether the FDA has accepted the request for filing or review.

VI. 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.

VII. The status of each request for authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j for the Brand Style, including as applicable:

a. The date of any FDA Marketing Denial Order (MDO), Not Substantially Equivalent (NSE), and Not Exempt Order for the Brand Style.

b. The date of any rescission by FDA of any MDO, NSE, and Not Exempt Order for the Brand Style.

c. The date of any stay by FDA of any MDO, NSE, and Not Exempt Order for the Brand Style.

d. If review by a court of competent jurisdiction of any MDO, NSE, or Not Exempt Order applicable to the Brand Style has been sought, the name of the reviewing court, case number, and date of the initial case filing.

e. If a reviewing court of competent jurisdiction has stayed or vacated any MDO, NSE, or Not Exempt Order applicable to the Brand Style, the name of the reviewing court, case number,

and date of the stay or vacatur. A copy of any order staying or vacating an MDO, NSE, or Not Exempt Order applicable to the Brand Style must also be submitted.

f. Whether the request for authorization, approval, or order for the Brand Style under 21 U.S.C. sections 387e(j) or 387j remains pending and under review by the FDA.

g. Whether a provisional Substantial Equivalence report under 21 U.S.C. section 387j(a)(2)(B) remains under review by FDA or has been removed from review by FDA.

h. Whether 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. If the applicant responds affirmatively, the applicant must identify and submit a copy of the rule, guidance, or other formal statement by the FDA.

ii. If formal authorization, approval, or order for the Brand Style has not been sought under 21 U.S.C. sections 387e(j) or 387j, selection of one or more of the following for why such authorization, approval, or order has not been sought:

I. The Brand Style does not contain nicotine from any source.

II. The Brand Style is a pre-existing tobacco product that was commercially marketed in the United States as of February 15, 2007.

a. If this is selected, specification of whether or not a Voluntary Pre-Existing Tobacco Product Status Determination Request has been submitted to the FDA.

b. If a Voluntary Pre-Existing Tobacco Product Status Determination Request has been submitted to the FDA relating to the Brand Style, the following information shall be provided: the FDA-Assigned Submission Tracking Number(s) for the Brand Style and the status of the Request (under review, FDA determined the Brand Style is a pre-existing tobacco product

and date of the decision, or "other" status). If the status is "other," a brief description of the status.

III. 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.

a. If this is selected, a copy of the rule, guidance, or other formal statement by FDA must be submitted.

IV. Formal authorization, approval, or order has not been sought for the Brand Style under 21 U.S.C. sections 387e(j) or 387j for another reason. If selected, the reason(s) why authorization, approval, or order has not been sought for the Brand Style under 21 U.S.C. sections 387e(j) or 387j must be provided.

(~~10~~9) Documents from the FDA sufficient to identify the Brand Style's current status under a pathway to market the Product, including the status of an application for formal authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j, and status of any Voluntary Pre-Existing Status Determinations Request.

(~~11~~10) Every determination regarding flavor in the Brand Style made by another government agency and received by Applicant.

(~~12~~11) Applicant may provide additional information or comments regarding the Brand Style that Applicant considers relevant to the Attorney General's determination as to whether the Brand Style is an unflavored Tobacco Product under Health & Safety Code section 104559.5.

(d) No product form or variant form will be accepted for any electronic device that is not sold with nicotine or liquid intended to be vaporized and inhaled from the device, or for any separately sold accessory, component, or part as those terms are defined in 21 Code of Federal Regulations, section 1100.3, unless that accessory, component, or part contains nicotine or liquid intended to be vaporized and inhaled ~~from the accessory, component, or part~~.

NOTE: Authority cited: Section 104559.1, Health and Safety Code. Reference: Section 104559.1, Health and Safety Code; Section 104559.5, Health and Safety Code; 21 Code of Federal Regulations, section 1100.3.

§ 946. Submission of variant form

(a) A variant form may be completed and submitted in place of a product form if the Brand Style sought to be included on the UTL is a Variant of a Predicate Brand Style and meets one of the Variant types described in subdivision (c). A UTL submission for a Variant is not complete until the UTL submission for the associated Predicate Brand Style is complete.

(b) Variant forms shall be completed and submitted through the Attorney General's UTL web portal. Upon a showing of good cause that outweighs the operational needs of the Attorney General, the Attorney General shall permit exceptions from use of the web portal for variant forms. For example, good cause may be found when the Applicant demonstrates that they lack access to the web portal due to lack of necessary technology or internet connectivity. Examples of operational needs that combined or individually may outweigh an Applicant's good cause include strains on staff resources that divert resources from more critical responsibilities and difficulties integrating data from outside of the web portal.

(c) A variant form may be used only for the following types of Variants:

(1) Variants with packaging designed for a market outside of California, including exports;

(2) Variants with different packaging or different Product count per package, unless the packaging itself 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 electronic devices.

(d) A variant form need not be submitted for a Brand Style that qualifies as a Variant, has the same external packaging as the Predicate Brand Style (or another Variant of the same Predicate Brand Style for which a variant form has already been submitted), but contains different internal packaging (for example, different phrases that are revealed once the package is opened), unless statements on the internal packaging implicitly or explicitly convey the presence of a characterizing flavor.

(~~d~~e) The Predicate Brand Style for all Variants other than a Multipack must be a Brand Style for which the Applicant submitted a product form. For Multipacks, the Predicate Brand Style may be

any Brand Style that appears on the UTL (whether a product form or variant form was originally submitted) or a Brand Style for which the Applicant completed a product form or variant form.

(~~e~~f) Applicant must specify on the variant form whether the Variant is a Multipack, and, if so, whether the Multipack contains a device and the name of the Multipack. If the Variant is not a Multipack, all the applicable categories from subdivision (c)(1) – (5) must be selected on the variant form.

(~~f~~g) The following information must be provided to complete a variant form:

(1) The applicable Variant type(s) from those listed in subdivision (c).

(2) For Variants of the type described in subdivision (c)(1), a description of the market shall also be provided.

(3) For Variants of the type described in subdivision (c)(2), if the packaging differs from the related Predicate Brand Style, a brief description of the Variant's packaging, the packaging's unique name (if any), and the difference in Product count per package (if any).

(4) For Variants of the type described in subdivision (c)(3), a brief description of the promotion or discount.

(5) For Variants of the type described in subdivision (c)(4), the language used.

(6) For Variants of the type described in subdivision (c)(6), a brief description of the Variant's packaging.

(7) For Variants of the type described in subdivision (c)(7), a brief description of the Variant's packaging, the device name, the device type, whether the device contains a lithium-ion battery, and the battery's capacity.

(8) All Predicate Brand Style(s) the Variant relates to.

(9) Whether the Variant has a ~~e~~Carton or ~~f~~Roll differing from the ~~e~~Carton or ~~f~~Roll for which information was provided in the product form for the Predicate Brand Style(s);

(10) Universal product code for the Variant and any ~~e~~Carton or ~~f~~Roll of that Variant differing from the ~~e~~Carton or ~~f~~Roll for which information was provided in the product form for the Predicate Brand Style(s); and manufacturing stock keeping unit number for the Variant and any ~~e~~Carton or ~~f~~Roll of that Variant differing from the ~~e~~Carton or ~~f~~Roll for which information was provided in the product form, if there is no universal product code.

(11) If the information provided for the Predicate Brand Style under subdivisions (c)(~~9~~8) and (c)(~~10~~9) of Section 945 does not apply to the Variant, subdivisions (c)(~~9~~8) and (c)(~~10~~9) of Section 945 must be completed in the variant form. If the Applicant affirms that the information for the Predicate Brand Style under subdivisions (c)(~~9~~8) and (c)(~~10~~9) of Section 945 does apply to the Variant, the Attorney General will consider the Variant's FDA information to be identical to that of the Predicate Brand Style, and therefore incorporated into the variant form.

(12) A design file or photos of the Variant Product packaging as described in Section 945, subdivision (c)(7), except ~~c~~Carton or ~~r~~Roll design files and photos need not be provided if the ~~c~~Carton or ~~r~~Roll is identical to that of the Predicate Brand Style's ~~c~~Carton or ~~r~~Roll.

~~(13) Written description of images depicted in the design file or photos as described in subdivision (c)(8) of Section 945.~~

~~(14)~~(13) Any determinations regarding flavor as described in Section 945, subdivision (c)(~~11~~10) if they are distinct from determination(s) included in the product form for the Predicate Brand Style.

~~(15)~~(14) A confirmation that the information submitted about the items listed in Section 945, subdivisions (c)(1), (c)(3) - (c)(5), (c)(6)(B)-(K), and (c)(6)(M)-(N), on the product form for the Predicate Brand Style accurately describes the Variant. If the Variant differs from the Predicate Brand Style with respect to any of the information submitted on the most recent product form for the Predicate Brand Style regarding the items listed in those subdivisions, a variant form may not be submitted for the Brand Style. Instead, a ~~new~~ product form shall be completed and submitted.

~~(16)~~(15) Applicant may provide additional information or comments regarding the Brand Style that Applicant considers relevant to the Attorney General's determination as to whether the Brand Style is an unflavored Tobacco Product under Health & Safety Code section 104559.5.

NOTE: Authority cited: Section 104559.1, Health and Safety Code. Reference: Section 104559.1, Health and Safety Code; Section 104559.5, Health and Safety Code.

§ 947. Request for Placement on the Unflavored Tobacco List

(a) To request placement of a Brand Style on the UTL, Certifying User for the Applicant shall submit a UTL application using the UTL application form on the Attorney General's UTL web portal. The UTL application cannot be submitted for a Brand Style until a product form or variant form for the Brand Style has been completed and submitted as detailed in Sections 945 and 946. UTL applications may be submitted at any time.

(b) To complete the UTL application form, the following information shall be provided:

(1) The Brand Style(s) requested to be placed on the UTL;

(2) A certification that no Brand Style requested to be placed on the UTL has a Characterizing Flavor;

(3) A waiver of any sovereign immunity defense that may apply in an action to enforce the provisions of Health and Safety Code section 104559.1 or to enforce regulations adopted under Health and Safety Code section 104559.1;

(4) Consent to the jurisdiction of the California courts for the purpose of enforcement of Health and Safety Code section 104559.1 and for enforcement of regulations adopted under Health and Safety Code section 104559.1; and

(5) Confirmation that a sample of each Brand Style (including, as appropriate, the ~~€~~Carton or ~~₹~~Roll for the Brand Style) will be shipped with a packing slip to the address and contact provided in the instructions on the UTL application. The packing slip is provided upon submission of a UTL application. A sample is required for every Brand Style unless the Brand Style is a Variant of a Predicate Brand Style for which a UTL application has been submitted under this section. The sample must include the largest packaging unit of the Brand Style marketed for retail sale, generally meaning the ~~€~~Carton or ~~₹~~Roll, if applicable, in assembled packaging (not flat packed). The sample must also include the consumable Tobacco Product in the smallest packaging unit marketed for retail sale included on the product form. For example, an Applicant may satisfy the sample requirement by providing (1) an exemplar of the Tobacco Product in the smallest packaging unit marketed for retail sale and an empty, assembled version of its largest packaging unit (e.g., a pack of cigarettes and the empty, assembled carton for those cigarette packs satisfies the sample requirement for the pack and the carton), (2) the largest packaging unit (e.g., a sample carton containing 10 packs of cigarettes satisfies the sample requirement for the carton and the pack), or (3) if no ~~€~~Carton or ~~₹~~Roll is identified

on the form, the full packaging unit identified on the form. A UTL application is not considered complete until the required sample is received by the Attorney General.

(c) An Applicant, through a Certifying User, must 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 and correct. If the Attorney General deems information submitted about a Brand Style in a UTL application or associated product form or variant form to be intentionally false, the Attorney General shall decline to list the Brand Style on the UTL or initiate removal of the Brand Style under Section 950.

(d) Payment of the required applicable fees must be made through the online payment system in the amount designated by Section 954 to complete the submission of the UTL application form. Upon a showing of good cause, the Attorney General may permit exceptions from use of the online payment system. For example, good cause may be found when the Applicant demonstrates that they lack access to the online payment system due to lack of necessary technology or internet connectivity.

(e) A completed UTL application must be submitted and approved for each Brand Style, even if similar Brand Styles are listed on the UTL. A Brand Style that has not been approved through a UTL application is a flavored Tobacco Product under Health and Safety section 104559.1, subdivision (g).

(f) The Attorney General will respond within ninety (90) days of the submission of a complete UTL application. A response will be an approval, a denial, or a request for additional information under Section 949.

NOTE: Authority cited: Section 104559.1, Health and Safety Code. Reference: Section 104559.1, Health and Safety Code.

§ 948. Impact of FDA Status on Listing and Removal

(a) A Brand Style that requires formal premarket authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j, but has not received such authorization, approval, or order is ineligible for listing on the UTL unless:

(1) The Brand Style contains nicotine derived from tobacco; the Brand Style was brought within the regulatory authority of the FDA under the May 10, 2016 Deeming Rule, 81 Federal Register 28973 through 29104; the Brand Style was marketed in the United States as of August 8, 2016; and the Brand Style has an application for formal authorization, approval, or order that was submitted to the FDA on or before September 9, 2020, was accepted for filing or review, and remains pending;

(2) The Brand Style contains nicotine derived from a source other than tobacco; the Brand Style was marketed in the United States as of April 14, 2022; and the Brand Style has an application for formal authorization, approval, or order that was submitted to the FDA on or before May 14, 2022, was accepted for filing or review, and remains pending; or,

(3) The Brand Style meets the criteria of subdivisions (a)(1) or (a)(2) of this Section, except the Brand Style no longer has a pending application with the FDA for formal authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j because a negative action on that application is stayed, rescinded by the FDA, or vacated by a court of competent jurisdiction.

(b) The Attorney General shall not exclude a Brand Style from the UTL under subdivision (a) of this Section for lacking formal premarket authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j if the Applicant demonstrates:

(1) 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, or,

(2) The Brand Style has been deemed to be within the FDA's regulatory authority under 21 U.S.C. section 387a or otherwise brought within the FDA's authority by statute or court order; the Brand Style was marketed in the United States as of the date it was deemed or otherwise brought within FDA's regulatory authority; and the Manufacturer or Importer of the Brand Style has submitted an application for formal authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j by the deadline established by the FDA that was accepted by the FDA for filing or review and remains pending, or has received a negative action that is stayed, rescinded by the FDA, or vacated by a court of competent jurisdiction.

(c) The Attorney General shall not exclude a Brand Style from the UTL under subdivision (a) 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.

NOTE: Authority cited: Section 104559.1, Health and Safety Code. Reference: 21 U.S.C. Sections 387a, 387e, 387j; *Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 81 Fed. Reg. 28973-29104 (May 10, 2016), Docket No. FDA-2014-N-0189.

§ 949. Requests for Additional Information

(a) After a Brand Style is submitted for inclusion on the UTL via a product form or variant form in a UTL application, whether that Brand Style has been included on the UTL or not, the Attorney General may request additional information substantiating Applicant's contention that the Brand Style lacks a Characterizing Flavor. The Attorney General's request for additional information may require Applicant to provide ingredient information, a consumer survey, or other information that the Attorney General deems necessary to substantiate Applicant's contention that the Brand Style lacks a Characterizing Flavor. In addition to the information or factual substantiations requested by the Attorney General, Applicant may also include in its response any other information Applicant deems relevant to substantiate its contention that the Brand Style lacks a Characterizing Flavor. Applicant shall have thirty (30) days to respond to a request for additional information. The Attorney General shall decline to list the Brand Style on the UTL or initiate removal of the Brand Style from the UTL under subdivision (c) of Section 950 if Applicant fails to timely respond to a request for additional information.

(b) In addition, the Attorney General may require Applicant to provide information and documentation regarding a Brand Style's packaging, marketing, or status with the FDA. Applicant shall have fifteen (15) days to respond to a request made under this subdivision, unless the Attorney General extends the deadline pursuant to Section 944. The Attorney

General shall decline to list the Brand Style on the UTL or initiate removal of the Brand Style from the UTL under subdivision (c) of Section 950 if Applicant fails to timely respond to a request for status, packaging, or marketing information.

(c) No later than thirty (30) days after the receipt of Applicant's timely response to the request for additional information, the Attorney General shall:

(1) Notify Applicant that the Brand Style is approved to be listed on or remain on the UTL.

(2) Send Applicant a request under subdivision (a) for additional information substantiating Applicant's contention that a Brand Style lacks a Characterizing Flavor;

(3) Send Applicant a request under subdivision (b) for additional information and documentation regarding a Brand Style's packaging, marketing, or status with the FDA; or

(4) Notify Applicant that the Attorney General declines to list the Brand Style on the UTL or is initiating removal of the Brand Style from the UTL under subdivision (c) of Section 950.

NOTE: Authority cited: Section 104559.1, Health and Safety Code. Reference: Section 104559.1, Health and Safety Code.

§ 950. List Removal

(a) Notwithstanding the previous placement of a Brand Style on the UTL, 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.

(b) The Attorney General shall initiate removal from the UTL any Brand Style that is ineligible for listing under Section 948.

(c) The Attorney General shall initiate removal of a Brand Style from the UTL under subdivision (a) or (b) of this Section or Sections 947, 948, 949, 951, or 952 by providing Applicant of a Brand Style a notice of initiation of removal identifying the basis for the Attorney General's removal of the Brand Style and communicating the Attorney General's intention to remove the Brand Style from the UTL in sixty (60) days, or, for removals under Section 951, on or after June 30 of that year. The Attorney General shall notify Applicant of any modifications to the notice of initiation of removal if the basis for the removal changes.

(d) Pursuant to Health and Safety Code section 104559.1, subdivision (f)(2)(B), thirty (30) days after the notice of initiation of removal or modified notice is provided to Applicant under subdivision (c) of this Section, the Attorney General shall provide Applicant a final notice of removal identifying the basis for the Attorney General's determination. The final notice of removal shall notify Applicant that the Brand Style will be removed in thirty (30) days from the date of the final notice of removal, or, for removals under Section 951, on or after June 30 of that year. 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 at https://utl.doj.ca.gov communicating the Attorney General's intention to remove the Brand Style from the UTL in thirty (30) days, or, for removals under Section 951, on or after June 30 of that year.

(e) On the same day a Brand Style is removed from the UTL, a public notice will be posted on the Attorney General's website at https://utl.doj.ca.gov communicating the Brand Style's removal from the UTL.

(f) If at any time after Applicant receives a notice of initiation of removal or modified notice under subdivision (c) of this Section and before actual removal of the Brand Style from the UTL under subdivision (e) of this Section, Applicant provides additional materials to the Attorney General that modify the Attorney General's determination to remove the Brand Style under subdivision (a)-(b) of this Section or Sections 947, 948, 949, 951, or 952, the Attorney General shall notify Applicant of the modified determination and, if a public notice of the Attorney General's intention to remove was posted under subdivision (d) of this Section, a public notice will be posted of the modified determination on the Attorney General's website at https://utl.doj.ca.gov. A modified determination will rescind or alter the Attorney General's original determination to remove the Brand Style.

NOTE: Authority cited: Section 104559.1, Health and Safety Code. Reference: Section 104559.1, Health and Safety Code.

§ 951. Renewals

(a) If a Brand Style is on the UTL as of March 31 of any given year, a renewal application must be submitted as described in subdivision (b) for that Brand Style between April 1 and April 15 of such year to remain on the UTL. If a Brand Style is not renewed, the Attorney General

shall initiate removal under subdivision (c) of Section 950, which will be effective on or after June 30 of that fiscal year.

(b) A renewal application must be submitted on the UTL web portal. Completion of a renewal application requires selection of the Brand Style(s) to be renewed and certification under penalty of perjury that the Certifying User has reviewed, on behalf of the Applicant, the most recent product form or variant form submitted for each Brand Style to be renewed and that all of the information on the product form or variant form is accurate.

(c) In order to complete submission of a renewal application, the annual renewal fee under subdivision (c) of Section 954 for each Brand Style must be paid through the online payment system on the Attorney General's UTL web portal ~~must be paid~~. Upon a showing of good cause, the Attorney General may permit exceptions from use of the online payment system. For example, good cause may be found when the Applicant demonstrates that they lack access to the online payment system due to lack of necessary technology or internet connectivity.

NOTE: Authority cited: Section 104559.1, Health and Safety Code. Reference: Section 104559.1, Health and Safety Code.

§ 952. Updates

(a) Except as provided in subdivision (b)~~,~~ and Section 945, a new UTL application, as described in Section 947, and a new product form or variant form must be completed for a Brand Style listed on the UTL when there are changes to any information provided in the current product form or variant form regarding the Brand Style or if the business ownership of Applicant of the Brand Style has changed.

(b) Changes of the types listed in subdivisions (b)(1) through (b)(4) shall be submitted on the Attorney General's UTL web portal no later than fifteen (15) days after the change. The Brand Style must be selected in the "View Brand Styles" link, and changes must be provided through the "Edit" tab. The Applicant, through a Certifying User, must also certify under penalty of perjury that the updated statements in the product form or variant form are true and correct. Changes made through the "Edit" tab will update the product form or variant form for the Brand Style selected. Changes to a Predicate Brand Style will update the

information for the variant form unless the variant form contains different FDA information and documents.

(1) Trademark information, as detailed in Section 945, subdivision (c)(3);

(2) FDA information, as detailed in Section 945, subdivision (c)(9);

(3) FDA documents, as detailed in Section 945, subdivision (c)(10); and

(4) Additional flavor determinations, as detailed in Section 945, subdivision (c)(11).

~~(5) A change to a Brand Style in manufacturing materials or process that is not distinguishable by an ordinary consumer and that does not alter the flavor in a distinguishable way. Examples of such changes may include replacing a cigarette's tipping paper with tipping paper from a new source or adjustment of under a millimeter in a cigarette's size. Minor variations due to a Brand Style being manufactured by hand do not require an update. A change under this subdivision must be identified by emailing Attorney General at UTLInbox@doj.ca.gov with reference to the submission ID for the Brand Style no later than fifteen (15) days after the change.~~

(c) If Applicant fails to comply with subdivision (a) or (b), the Attorney General shall initiate removal of the Brand Style from the UTL under subdivision (c) of Section 950.

NOTE: Authority cited: Section 104559.1, Health and Safety Code. Reference: Section 104559.1, Health and Safety Code.

§ 953. Designation of Confidential Information

(a) Information and documentation designated nonpublic and submitted under subdivisions (c)(~~9~~8) and (c)(~~10~~9) of Section 945, subdivision (~~f~~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 (Division 10 (commencing with section 7920.000) of Title 1 of the Government Code), with the exception of the following publicly disclosable FDA status designations:

(1) "FDA authorization, approval, or order received," if, under subdivision (c)(~~9~~8) of Section 945, the Brand Style has received formal authorization, approval, or order from the FDA under 21 U.S.C. sections 387e(j) or 387j.

(2) "Under Review by FDA," if, under subdivision (c)(~~9~~8)(B) of Section 945, formal authorization, approval, or order for the Brand Style has been sought under 21 U.S.C. sections 387e(j) or 387j, and, under subdivision (c)(~~9~~8)(B)(i)(VII)(f) of Section 945, a request for authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j remains pending and under review by the FDA or, under subdivision (c)(~~9~~8)(B)(i)(VII)(g) of Section 945, a provisional Substantial Equivalence report under 21 U.S.C. section 387j(a)(2)(B) remains under review by FDA.

(3) "Negative action on application stayed or rescinded by FDA," if, under subdivision (c)(~~9~~8)(B) of Section 945, formal authorization, approval, or order for the Brand Style has been sought under 21 U.S.C. sections 387e(j) or 387j, and, under subdivision (c)(~~9~~8)(B)(i)(VII)(b) or (c)(~~9~~8)(B)(i)(VII)(c) of Section 945, a Marketing Denial Order (MDO), Not Substantially Equivalent (NSE), or Not Exempt Order for the Brand Style was stayed or rescinded by the FDA.

(4) "Negative action on application stayed or vacated by court," if, under subdivision (c)(~~9~~8)(B) of Section 945, formal authorization, approval, or order for the Brand Style has been sought under 21 U.S.C. sections 387e(j) or 387j, and, under subdivision (c)(~~9~~8)(B)(i)(VII)(e) of Section 945, a Marketing Denial Order (MDO), Not Substantially Equivalent (NSE), or Not Exempt Order for the Brand Style was stayed or vacated by a court of competent jurisdiction.

(5) "Provisional Substantial Equivalence Product Removed From Review under 21 U.S.C. section 387j(a)(2)(B)", if, under subdivision (c)(~~9~~8)(B) of Section 945, formal authorization, approval, or order for the Brand Style has been sought under 21 U.S.C. sections 387e(j) or 387j, and, under subdivision (c)(~~9~~8)(B)(i)(VII)(g) of Section 945, a provisional substantial equivalence report was submitted under 21 U.S.C. section 387j(a)(2)(B) and removed from review by the FDA.

(6) "FDA authorization, approval, or order not sought," if, under subdivision (c)(~~9~~8)(B) of Section 945, authorization, approval, or order for the Brand Style has not been

sought under 21 U.S.C. sections 387e(j) or 387j for one of the reasons identified under subdivision (c)(8)(B)(ii) of Section 945.

(7) "FDA authorization, approval, or order denied," if, under subdivision (c)(~~9~~8)(B) of Section 945, formal authorization, approval, or order for the Brand Style has been sought under 21 U.S.C. sections 387e(j) or 387j, and, under subdivision (c)(~~9~~8)(B)(i)(VII)(a), a Marketing Denial Order (MDO), Not Substantially Equivalent (NSE), or Not Exempt Order for the Brand Style was received and has not been rescinded or stayed by FDA under subdivisions (c)(~~9~~8)(B)(i)(VII)(b) or (c)(~~9~~8)(B)(i)(VII)(c) of Section 945 or stayed or vacated by a court of competent jurisdiction under subdivision (c)(~~9~~8)(B)(i)(VII)(e) of Section 945.

(8) "FDA issued 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," if under subdivision (c)(8)(B) of Section 945, formal authorization, approval, or order for the Brand Style has been sought under 21 U.S.C. sections 387e(j) or 387j, and, under subdivision (c)(8)(B)(i)(VII)(h) of Section 945, the Applicant indicates 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.

(b) Information and documentation submitted under subdivision (b) of Section 949 and design files submitted under subdivision (c)(7) of Section 945 or subdivision (~~f~~g)(12) of Section 946 that are designated as nonpublic shall be considered additional information and documentation regarding a Brand Style's status with the FDA, packaging, and marketing 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.

(c) Additional information and documentation submitted under subdivision (f) of Section 950 that relates to a removal decision based on Brand Style's characterizing flavor or FDA status is considered confidential and proprietary information under Health and Safety Code section 104559.1, subdivision (f)(2)(D), that is not subject to disclosure under the California Public Records Act.

(d) The Attorney General shall consider the following to be additional information and factual substantiation regarding a Brand Style's lack of Characterizing Flavor that is confidential and

proprietary under Health and Safety Code section 104559.1, subdivision (b)(2)(B), and not subject to disclosure under the California Public Records Act:

(1) Information and factual substantiation regarding a Brand Style's lack of Characterizing Flavor in a product form or variant form provided under subdivisions (c)(~~11~~10) and (c)(~~12~~11) of Section 945, subdivisions (~~f~~g)(~~14~~13) and (~~f~~g)(~~16~~15) of Section 946, or subdivision (b)(4) of Section 952 through the Attorney General's UTL web portal or by other means approved by the Attorney General; and

(2) Information and factual substantiation regarding a Brand Style's lack of Characterizing Flavor provided in response to requests for additional information by the Attorney General under subdivisions (a) of Section 949.

(e) The Attorney General may disclose confidential and proprietary information received from UTL Applicants to third-party consultants designated by the Attorney General, provided the recipient agrees in writing to maintain the confidentiality of the information.

NOTE: Authority cited: Section 104559.1, Health and Safety Code. Reference: Section 104559.1, Health and Safety Code.

§ 954. Application Fees

(a) The initial application fee for each Brand Style submitted for inclusion on the UTL is $300, except as provided in subdivision (b). If the business ownership of the Manufacturer or Importer of a Brand Style changes following the submission of a UTL application for that Brand Style, a new application with accompanying product form and initial application fee must be submitted by the new owner.

(b) A Variant Fee of $150 shall apply to each Variant listed on a UTL application and submitted for inclusion on the UTL.

(c) The annual Renewal Fee for each Brand Style is $150, regardless of how it was originally submitted for inclusion on the UTL.

(d) All fees under this Section shall apply to the current fiscal year ending June 30 and shall not be prorated.

(e) A request for placement of a Brand Style on the UTL shall not be considered by the Attorney General until the required initial application fee, Variant Fee, or Renewal Fee is paid in full.

A Brand Style for which a Renewal Fee is not received by April 30 will be subject to removal from the UTL by the Attorney General on or after June 30 of that fiscal year pursuant to the removal process identified in subdivisions (b)-(d) of Section 950.

NOTE: Authority cited: Section 104559.1, Health and Safety Code. Reference: Section 104559.1, Health and Safety Code.

Article 3. Penalty Citations and Appeals

§ 955. Penalty Citations

(a) To assess civil penalties under Health and Safety Code section 104559.1, subdivision (o)(3), against the distributor, wholesaler, or delivery seller, the Attorney General will either bring a civil action brought in the name of the People of the State of California or serve a written citation by personal service or certified mail that states the basis of the violation and the amount of the penalty.

(b) In determining the amount assessed, the Attorney General will take into consideration all relevant circumstances, including:

(1) The nature and severity of the violation.

(2) History of violations of the same or similar nature.

(3) The good or bad faith exhibited by the cited person or entity.

(4) The extent to which the cited person or entity has cooperated with the Attorney General.

(5) The size and resources of the cited person or entity.

(c) Upon the date of personal service or upon the date of receipt by certified mail, the citation shall be considered to have been issued and service shall be considered to be complete.

(d) All penalties shall be paid no later than thirty (30) days after service of the citation, unless a timely appeal has been filed under Section 956 or the Attorney General has agreed to a later date in writing.

NOTE: Authority cited: Section 104559.1, Health and Safety Code. Reference: Section 104559.1, Health and Safety Code.

§ 956. Appeals

(a) An appeal of a citation under Section 955 must be submitted to the Attorney General no later than thirty (30) days after service of the citation or the right to appeal is waived and the citation becomes the final order of the Attorney General. An appeal of a citation must be in writing to the Attorney General at UTLinbox@doj.ca.gov and include: the name of the cited person or entity; address, email, and telephone number of the person or entity appealing; and a statement of the basis of appeal.

(b) Notice of the appeal hearing date, time, and place shall be provided to the person or entity appealing the citation in accordance with the procedures set out in section 11509 of the Government Code. The failure of the person or entity to appear at the time and place of the hearing shall be deemed a withdrawal of the appeal, and the citation shall constitute the Attorney General's final order subject to no further administrative review.

(c) All appeal hearings provided for under this section shall be conducted by an administrative hearing officer designated by the Attorney General. The hearing officer shall not have participated in the decision concerning the administrative action that is the subject of the hearing and is otherwise subject to the disqualification provisions of sections 11425.30 and 11425.40 of the Government Code.

(d) All hearings under this regulation shall 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, except for provisions requiring the designation of administrative law judges and any other provision of Chapter 5 of Part 1 of Division 3 of Title 2 of the Government Code that is inconsistent with these regulations.

NOTE: Authority cited: Section 104559.1, Health and Safety Code. Reference: Section 104559.1, Health and Safety Code.

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

(a) No later than fifteen (15) days after service of the hearing officer's proposed decision on an appeal as provided for in Chapter 5 (commencing with section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, any party to the administrative action may file a written brief served on all parties seeking review by the Attorney General of the proposed decision. Failure of a party to timely file such a brief waives the party's right to such a review.

(b) Briefing Procedure

(1) No later than fifteen (15) days after service of the written brief requesting review of the proposed decision, an opposition to the request (if any) must be filed and served on the parties.

(2) Any brief requesting review of the proposed decision, and any opposition brief shall address the following:

(A) Whether the facts stated in the proposed decision are consistent with the evidence presented;

(B) Whether the proposed decision contains an accurate statement and/or application of the law; and,

(C) Whether additional evidence exists that could not, with reasonable diligence, have been discovered and presented at the administrative hearing.

(c) Upon completion of the briefing process, the Attorney General may do any of the following:

(1) Adopt the proposed decision in its entirety.

(2) Reduce or otherwise mitigate the proposed decision in its entirety.

(3) Make technical or non-substantive changes, which do not affect the factual or legal basis of the proposed decision, and adopt it as the final decision.

(4) Not adopt the proposed decision. If the proposed decision is not adopted, the Attorney General may decide the case upon the record, including the transcript, or may refer the case back to the hearing officer to take additional evidence. If the case is remanded back to the hearing officer for additional evidence, another proposed decision shall be prepared based upon this additional evidence. The proposed decision shall be subject to the review and adoption procedures set out in these regulations.

(d) The proposed decision shall be deemed adopted by the Attorney General 100 days after service of the proposed decision by the hearing officer, unless within that time: (1) the Attorney General notifies the parties that the proposed decision is or is not adopted or is otherwise modified, or (2) the matter is referred to the hearing officer to take additional evidence.

(e) The Attorney General may reasonably extend the time limits in subdivisions (a) and (b).

NOTE: Authority cited: Section 104559.1, Health and Safety Code. Reference: Section 104559.1, Health and Safety Code.