## CALIFORNIA DEPARTMENT OF JUSTICE

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

#### STD 399 ATTACHMENT A

**Economic Impact Statement** 

Section B – Estimated Costs

**Business Costs** 

Business costs for products submitted for inclusion on the UTL in Fiscal Year 2025-2026

As further detailed under Fiscal Impact Statement, Section B – Fiscal Effect on State Government, the Department estimates receiving approximately 7,415 unique tobacco products for listing on the Unflavored Tobacco List (UTL) in Fiscal Year 2025-2026. Based on an estimated average of ten unique tobacco products submitted per Manufacturer or Importer for inclusion on the UTL in Fiscal Year 2025–2026, the Department projects that it will receive applications from approximately 741.5 entities. The Department estimates that approximately half of submissions will be for products submitted on the product form (under Section 945 of the proposed regulations) that require a \$300 per-product application fee and the other half will be for products submitted on the variant form (under Section 946 of the proposed regulations) that require a \$150 per-product application fee, resulting in a total average cost in fees per Manufacturer or Importer of approximately \$2,250. The Department's payment processor requires a convenience fee of 2.3% for credit card transactions; however, the Department is also accepting payments by checks with no associated convenience or processing fees.

Manufacturers and Importers are required to send the Department samples of products submitted on the product form; the Department estimates that each product costs \$10 to manufacture and \$30 to ship, and so, assuming the average Manufacturer or Importer submits five products for inclusion on the UTL during Fiscal Year 2025-2026, the Department estimates that, on average, each Manufacturer will incur approximately \$200 to submit product samples to the Department. If a Manufacturer or Importer associates a carton or roll with a product submitted on the product form, the Department requires a sample of the associated carton or roll as well. The Department estimates that each Manufacturer or Importer will, on average, associate a carton or roll in 20% of product form submissions for listing during Fiscal Year 2025-2026, and the Department estimates that each carton or roll will cost \$100 to manufacture and \$60 to ship, for a total additional cost of \$160 per Manufacturer or Importer for providing samples of associated cartons

<sup>&</sup>lt;sup>1</sup> The figure of 741.5 represents a statistical average derived from dividing the total number of estimated products (7,415) by the average number of products submitted per Manufacturer or Importer (10). This does not imply the existence of a partial Manufacturer or Importer, but rather serves as a quantitative projection of the total number of businesses expected to participate.

or rolls. Thus, the total estimated average cost is \$360 per Manufacturer or Importer to provide samples.

The Department estimates that, on average, it will take approximately 30 minutes to complete an application for a product submitted on the product form and 15 minutes to complete an application for a product submitted on the variant form. Thus, assuming a wage of \$50 per hour to prepare application materials, the Department estimates a total average cost of \$187.50 per Manufacturer or Importer to submit applications for five products via the product form and five products via the variant form.

Thus, taking into account the time needed to fill out a product, variant, or renewal application, and applicable shipping costs to provide a product sample, the average estimated cost to apply for UTL placement per application type is:

- <u>Product</u>: \$300 registration fee + \$10 sample at \$30 shipping cost + \$25 application preparation time = \$365
- Product with associated carton or roll: \$300 registration fee + \$10 product sample at \$30 shipping cost + \$100 carton/roll at \$60 shipping cost + \$25 application preparation time = \$525
- <u>Variant</u>: \$150 registration fee + \$12.50 application preparation time = \$162.50
- Renewal: \$150 registration fee + \$8.33 application preparation time = \$158.33

Estimated Average Costs Per-Business for FY 2025-2026 UTL Listings						
Submissions Fees	omissions Fees Samples Application					
	_	Preparation	Cost			
\$2,250	\$360	\$187.50	\$2,797.50			

Based on the estimates above, the total average cost for a Manufacturer or Importer to submit products for inclusion on UTL in Fiscal Year 2025-2026 is estimated to be approximately \$2,797.50, and the total estimated cost for all tobacco product Manufacturers and Importers (estimated at 741.5 businesses) to submit products for inclusion on UTL in Fiscal Year 2025-2026 is estimated to be approximately \$2,074,346.25.

Business costs for products submitted for inclusion on UTL in Fiscal Years 2026-2027 and 2027-2028

As further detailed below under Fiscal Impact Statement, Section B – Fiscal Effect on State Government, the Department estimates approximately 7,415 unique tobacco products will be submitted annually for listing on the UTL in both Fiscal Years 2026-2027 and 2027-2028, with approximately 90% of submissions for renewals that require a \$150 per-product renewal fee, 5% for products submitted on the variant form that require a \$150 per-product renewal fee, and the remaining 5% for products submitted on the product form that require a \$300 per-product application fee. Averaging these costs across approximately 741.5 businesses, the Department estimates the cost in fees per Manufacturer or Importer will be approximately \$1,575.

Tobacco product samples are only required for products that are newly submitted on the product form, which the Department estimates will account for approximately 5% of the estimated 7,415 unique tobacco products annually submitted for listing on the UTL in both Fiscal Years 2026-2027 and 2027-2028. Based on the Department's estimate that each product submitted via the product form costs \$10 to manufacture and \$30 to ship, the average cost will be approximately \$20 per Manufacturer or Importer for samples. The Department further estimates that it approximately 20% of new product form submissions (or 74.15 product form submissions) will be associated with a carton or roll, and that each carton or roll will cost approximately \$100 to manufacture and \$60 to ship. Based on an estimated 741.5 Manufacturers and Importers, the Department estimates an average cost of \$16 per Manufacturer or Importer to provide samples of associated cartons or rolls. Thus, for products submitted for listing on the UTL in Fiscal Years 2026-2027 and 2027-2028, the average annual estimated cost is \$36 per Manufacturer or Importer to provide product samples.

The Department estimates that, on average, it will take approximately 10 minutes to recertify a product, 30 minutes to complete an application for using the product form, and 15 minutes to complete an application using the variant form. By calculating the total hours required for different types of applications—renewals, product form submissions, and variant form submissions—the total cost at \$50 per hour for products annually submitted for listing on the UTL in Fiscal Years 2026-2027 and 2027-2028 is estimated to be \$69,515.63. Averaged across an estimated 741.5 Manufacturers and Importers, the total estimated cost for application preparation is \$93.75 per Manufacturer or Importer.

Estimated Average Costs Per-Business for FY 2026-2027 & FY 2027-2028 UTL Listings					
Submissions Fees	Samples	Application	Total Annual		
		Preparation	Costs		
\$1,575	\$36	\$93.75	\$1,704.75		

Based on the estimates above, the total annual average cost for a Manufacturer or Importer to submit products for inclusion on UTL in Fiscal Years 2026-2027 and 2027-2028 is estimated to be approximately \$1,704.75, and the total average annual cost for all Manufacturers and Importers (estimated at 741.5 businesses) to submit products for inclusion on UTL in Fiscal Years 2026-2027 and 2027-2028 is estimated to be approximately \$1,264,072.13.

## **Individual Costs**

The proposed regulations do not impose initial costs or annual ongoing costs for individuals.

## Non-Quantifiable Impacts

Section 948 of the proposed regulations identify the circumstances in which the Attorney General will exercise discretion to exclude a product from the UTL under subdivision (e) of Health and Safety Code section 104559.1 when the Manufacturer or Importer 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. Although the Department's exclusion of certain tobacco products

from the UTL under Section 948 is discretionary, the excluded products are adulterated and/or misbranded and therefore already illegal under federal law. (See 21 U.S.C. § 331(a) [prohibiting the introduction into interstate commerce of any tobacco product that is adulterated or misbranded]; U.S. Food and Drug Administration, "Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products," <a href="https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products">https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products</a> (as of September 16, 2025) ["New tobacco products on the market without the required premarket authorization are adulterated and misbranded under the FD&C Act and are subject to FDA enforcement action."].) Thus, any economic impacts that result from their exclusion from the UTL are not solely attributable to the proposed regulations.

## Section D – Alternatives to Regulation

The Department previously considered a regulation mandating high-resolution photographs of all tobacco product sides as an alternative to requiring that Manufacturers and Importers submit a physical product sample. However, voluntary trials conducted with Manufacturers and Importers revealed significant issues, including inconsistent image quality and feedback that the technical specifications were overly burdensome. As a result, the Department's proposed regulations relax the photograph requirements and require physical product and packaging samples. This allows the Department to control the imaging process, ensuring the creation of uniform, high-quality reference photographs for accurate identification by on-site agencies. It also facilitates the comprehensive physical evaluation and testing of the products. The costs of providing tobacco product samples are estimated above.

The Department initially considered regulations that would have required a standard application and fee for each unique tobacco product submitted for inclusion on the UTL. However, based on early feedback from the industry, the Department developed the variant designation and submission process, as detailed in Section 946 of the proposed regulations. The variant process links variations of a tobacco product that should not alter its flavor to an underlying product submitted on the product form. This process eliminates the need for redundant administrative review of product flavor and significantly simplifies the application requirements for Manufacturers and Importers. Additionally, by removing the need for a separate flavor analysis, the fee for variant submissions is substantially less than the fee for products submitted via the product form.

The proposed regulations prescribe the use of the DOJ's official web portal, including several specific forms. The decision to require the web portal is based on two key factors:

- <u>Need for specific information</u>: The Department must collect certain information that varies by product type, a process most effectively managed through structured online forms.
- <u>Application volume and efficiency</u>: Due to the anticipated high volume of applications, the Department requires a centralized online database to process submissions efficiently and in a timely manner.

This approach offers benefits to both the Department and applicants. For the Department, it minimizes the need to request additional information, allowing for a more streamlined review. For applicants, it ensures a faster and more predictable response time.

## **Fiscal Impact Statement**

## Section B – Fiscal Effect on State Government

As explained below, the Department estimates that revenue generated by application fees will roughly cover the Department's costs for operating and maintaining the UTL.

## **Product Submission Estimates**

The number of unique tobacco products that will be submitted for inclusion on the initial publication of the UTL and in subsequent years is uncertain. Some Manufactures and Importers may choose not to submit their products to the UTL based on information not available to the Department, e.g., because the products are impermissibly flavored, because they require but lack authorization from the United States Food and Drug Administration (FDA), or because they are not sold in sufficient numbers to justify application for placement on the UTL.

The Department has estimated the number of potentially eligible tobacco products from multiple sources, including publicly available records of authorized tobacco products maintained by the FDA; product listings on the California Tobacco Directory; the tobacco directories of other states, including e-cigarette and vape directories like those in Alabama and North Carolina; public and commercial databases that track and collect identifiable stock keeping units; and consultations with industry participants.

Based on these sources, the Department anticipates total submissions of approximately 7,415 unique tobacco products, with a significant share of total stock keeping units for cigars that fall outside of the statute's "Premium Cigar" classification.<sup>2</sup> (See Health & Safety Code, § 104559.5(a)(13) [defining "premium cigar"]; Health & Safety Code, §§ 104559.5(e),104559.1(s)(3) [excluding premium cigars from flavor ban and eligibility for UTL].) The Department estimates approximately half of submissions will be for a products submitted via the product form (which require a \$300 per-product application fee), and half will be for products submitted via the variant form (which qualifies for the \$150 per-product fee), totaling approximately \$1,668,375 in expected revenue for products submitted for listing in Fiscal Year 2025-2026.

As the UTL is new, it is difficult to predict future reenrollment behavior. Company decisions to enroll (or reenroll) will depend on a variety of considerations. As the number of FDA-authorized unflavored tobacco products is relatively stable but growing, the Department anticipates there will be some annual turnover in the UTL as Manufacturers and Importers elect to list new or different products, but the overall number of listings are likely to remain stable. To this end, the

<sup>&</sup>lt;sup>2</sup> This total for the 2025–2026 Fiscal Year is an initial projection and is subject to change as the Department continues to receive and process applications. Projections for Fiscal Years 2026–2027 and 2027–2028 will be informed by the actual number of products submitted in Fiscal Year 2025–2026 and are also subject to change.

Department estimates that Manufacturers and Importers of approximately 10% of the tobacco products submitted to the UTL in Fiscal Year 2025-26 will not re-certify those tobacco products in Fiscal Year 2026-27, but that an equal number of previously unsubmitted products will be submitted to the UTL in FY 2026-27. Thus, the Department estimates that of the approximately 7,415 unique tobacco product applications will be submitted in FY 2026-27, approximately 5% will be for underlying products submitted via the product form that require a \$300 per-product application fee (\$111,225), and 5% will be for products submitted via the variant form that qualify for the \$150 per-product fee (\$55,612.50), totaling approximately \$166,837.50 in fee revenue for newly submitted tobacco products. The Department estimates the remaining 90% of products will be renewals that require \$150 renewal fee, equaling a total revenue estimate of \$1,001,025 for renewed products. Thus, the total estimated fee revenue for products submitted for listing in Fiscal Year 2026-2027 is approximately \$1,167,862.50. The Department estimates the same fee revenues for products submitted for listing in Fiscal Year 2027-2028, approximately \$1,167,862.50.

## **Program Cost Estimates**

The estimated annual fiscal expenses for the UTL are broken down on the following charts. The Department notes, however, that program costs are dependent on a number of unknown factors, including the total number of tobacco products that Manufacturers and Importers will submit for inclusion on the UTL (which, as explained above, is uncertain despite the Department's best estimates), as well as the number of products submitted to the UTL that appear to be falsely certified as unflavored and therefore require additional Department resources to investigate and potentially adjudicate. Because existing law permits the Department to assess penalties against wholesalers, distributors, and delivery sellers under subdivision (o)(3) of section 104559.1 of the Health and Safety Code, the Department does not forecast any additional recovery of penalties as a result of these regulations during the current or subsequent two fiscal years. The Department further notes that the January 10, 2025 Budget Change Proposal (BCP), 0820-107-BCP-2025-GB, identifies the additional positions required by the Department to operate and maintain the UTL, rather than the full operational and maintenance costs of the program. The charts below identify the Department's estimate of the full operational and maintenance costs of the program, including the costs of positions identified in the BCP and of additional positions within existing Department resources that are expected to be utilized for UTL work.

	Program Costs for Fiscal Year 2025-26								
Start-up Costs	Title	Positions	Months/ Hours	Annual Salary+Benefits	Annual OE+E	Annual Indirect	Total Position Cost		
	DAG IV	1.0	12	244,368	41,416	42,295	328,079		
	Assoc. Gov't Program Analyst	1.0	12	122,253	13,862	21,339	157,454		
	IT Spec. I		420	19,304	,	3,027	22,331		
	IT Spec. II		420	25,560		4,008	29,568		
Subtotal		2.0		411,485	55,278	70,669	537,432		

Regular			Months/	Annual	Annual	Annual	Total
Costs	Title	Positions	Hours	Salary+Benefits	OE+E	Indirect	Position Cost
	DAG IV	2.0	12	488,736	82,832	84,590	656,158
	Assoc. Gov't			122,253	13,862	21,339	157,454
	Program Analyst	1.0	12				
	IT Spec. I	1.0	12	137,240	23,002	25,115	185,357
	Legal Secretary	1.0	12	88,643	11,912	15,763	116,318
	Crime Analyst I		48	1,896		297	2,193
Subtotal		5.0		838,768	131,608	147,104	1,117,480
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Total		7		1,250,253	186,886	217,773	1,654,912

Program Costs for Fiscal Years 2026-27 and 2027-28									
		Months/	Annual		Annual				
Title	Positions	Hours	Salary+Benefits	Annual OE+E	Indirect	Total Position Cost			
DAG IV	2.0	12	488,736	122,832	84,590	696,158			
Assoc. Gov't	1.0	12	122,253	13,862	21,339	157,454			
Program Analyst									
IT Spec. I	1.0	12	137,240	23,002	25,115	185,357			
Legal Secretary	1.0	12	88,643	11,912	15,763	116,318			
Crime Analyst I		95	3,753	-	588	4,341			
Total	5.0		840,625	171,608	147,395	1,159,628			