

APPENDIX

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APPENDIX A

FILED

JUN 28 2023

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

R. J. REYNOLDS TOBACCO
COMPANY; et al.,

Plaintiffs-Appellants,

v.

ROB BONTA, in his official
capacity as Attorney General
of California; SUMMER
STEPHAN, in her official
capacity as District Attorney
for the County of San Diego,

Defendants-Appellees.

No. 23-55349

D.C. No.

3:22-cv-01755-CAB-
WVG

Southern District of
California, San
Diego

ORDER:

Before: SILVERMAN, R. NELSON, and BUMATAY,
Circuit Judges.

The motion for summary affirmance (Docket Entry
No. 6) is granted. *See R.J. Reynolds Tobacco Co. v.
County of Los Angeles*, 29 F.4th 542 (9th Cir. 2022).

AFFIRMED.

APPENDIX B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

R.J. REYNOLDS TOBACCO COMPANY, et al, Plaintiffs,	Case No.: 22-cv-01755- CAB-WVG ORDER GRANTING MOTION TO DISMISS [Doc. Nos. 31, 32]
v. ROBERT BONTA, in his official capacity as Attorney General of California; and SUMMER STEPHAN, in her official capacity as District Attorney for the County of San Diego, Defendants.	

This matter is before the Court on Defendants’ motion to dismiss [Doc. No. 31].¹ The motion has been fully briefed, and oral argument was held on March 14, 2023. For the reasons set forth below, the motion is **GRANTED**.

¹ Defendant Summer Stephan filed a motion for joinder [Doc. No. 32] in Defendant Attorney General Bonta’s motion to dismiss. The ruling on this motion to dismiss applies to both Defendants.

I. BACKGROUND

In November 2022, California voters approved Senate Bill 793 (“S.B. 793”), a bill prohibiting the retail sale of “flavored tobacco products” within the State of California. S.B. 793 as codified states that “a tobacco retailer, or any of the tobacco retailer’s agents or employees, shall not sell, offer for sale, or possess with intent to sell or offer for sale, a flavored tobacco product or a tobacco product flavored enhancer.” Cal. Health & Safety Code § 104559.5(b)(1). As mentioned in the Complaint, “the original motivation for California’s ban on flavored tobacco products was to prevent youth usage of tobacco products.” [Doc. No. 1 at ¶ 24]. The California legislature engaged in several deliberations prior to writing the final bill, considering statistics about youth usage of flavored tobacco products and evidence related to the deaths and harms caused by the sustained use of tobacco. [Doc. No. 31 at 12].

On November 9, 2022, immediately following the November 2022 election, Plaintiffs brought this lawsuit against Defendants Attorney General Robert Bonta and San Diego County District Attorney Summer Stephan. The Complaint alleges that S.B. 793 (1) is preempted by the Smoking Prevention and Tobacco Control Act, (“TCA”) Pub. L. No. 111-31, 123 Stat. 1776 (2009) and (2) violates the dormant Commerce Clause.² The Ninth Circuit’s decision in

² Plaintiffs also filed a motion for preliminary injunction and injunction pending appeal [Doc. No. 13] pertaining to their Preemption claim. This Court denied that motion, and the denial was later affirmed by the Ninth Circuit. [Doc. No. 37].

R.J. Reynolds Tobacco Co. v. County of Los Angeles, 29 F.4th 542 (9th Cir. 2022), *cert. denied sub nom.*, *R.J. Reynolds Tobacco Co. v. County of Los Angeles, CA*, No. 22-338, 2023 WL 2227660 (U.S. Feb. 27, 2023), bars the Preemption claim. Thus, the only question for this Court to consider is whether Plaintiffs have sufficiently stated a claim under the dormant Commerce Clause.

II. STANDARD FOR REVIEW

Federal Rule of Civil Procedure 12(b)(6) permits a party to raise by motion the defense that the complaint “fail[s] to state a claim upon which relief can be granted”—generally referred to as a motion to dismiss. The Court evaluates whether a complaint states a recognizable legal theory and sufficient facts in light of Federal Rule of Civil Procedure 8(a)(2), which requires a “short and plain statement of the claim showing that the pleader is entitled to relief.” Although Rule 8 “does not require ‘detailed factual allegations,’ . . . it [does] demand . . . more than an unadorned, the defendant-unlawfully-harmed-me accusation.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim of relief that is plausible on its face.’” *Id.* (quoting *Twombly*, 550 U.S. at 570); *see also* Fed. R. Civ. P. 12(b)(6). A claim is facially plausible when the collective facts pled “allow . . . the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* There must be “more than a sheer possibility that a defendant has acted

unlawfully.” *Id.* Facts “merely consistent with a defendant’s liability” fall short of a plausible entitlement to relief. *Id.* (quoting *Twombly*, 550 U.S. at 557). The Court need not accept as true “legal conclusions” contained in the complaint, *id.*, or other “allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences,” *Daniels-Hall v. Nat’l Educ. Ass’n*, 629 F.3d 992, 998 (9th Cir. 2010).

III. DISCUSSION

Defendants argue S.B. 793 does not violate the dormant Commerce Clause because it does not directly regulate out-of-state commerce, favor in-state businesses, or impose excessive burdens on out-of-state commerce. Plaintiffs argue S.B. 793 violates the dormant Commerce Clause because it attempts to control the actions of out-of-state manufacturers. Plaintiffs fail to state a claim.

A. Dormant Commerce Clause

The Commerce Clause grants Congress the power to “regulate Commerce with foreign Nations, and among the several States, and with Indian tribes.” U.S. Const. art. I, § 8, cl. 3. The Clause “has long been understood to have a ‘negative’ aspect that denies the States the power unjustifiably to discriminate against or burden the interstate flow of articles of commerce.” *Oregon Waste Sys., Inc. v. Dep’t of Env’t Quality of State of Or.*, 511 U.S. 93, 98 (1994). This “dormant” Commerce Clause is “driven by concern about ‘economic protectionism—that is, regulatory measures designed to benefit in-state economic interests, by burdening out-of-state competitors.’” *Dep’t of Revenue of Ky. v. Davis*, 553 U.S. 328, 337-38 (2008) (quoting

New Energy Co. of Ind. v. Limbach, 486 U.S. 268, 273-74 (1998)).

The dormant Commerce Clause is violated if a state regulation discriminates against interstate commerce. “If a statute discriminates against out-of-state entities on its face, in its purpose, or in its practical effect, it is unconstitutional unless ‘it serves a legitimate local purpose, and this purpose could not be served as well by available nondiscriminatory means.’” *Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070, 1087 (9th Cir. 2013) (quoting *Maine v. Taylor*, 477 U.S. 131, 138 (1986)). The dormant Commerce Clause also bars states from discriminating against out-of-state entities by “directly control[ling] commerce occurring wholly outside the boundaries of a State,” also known as the extraterritoriality doctrine. *Healy v. Beer Inst. Inc.*, 491 U.S. 324, 336 (1989). Finally, if a state regulation is not discriminatory, it should be upheld, “unless the burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits.” *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

1. S.B. 793 Does Not Discriminate Against Out-Of-State Commerce

A statute is not “invalid merely because it affects in some way the flow of commerce between the states.” *Great Atl. & Pac. Tea Co. v. Cottrell*, 424 U.S. 366, 371 (1976). A statute that “treat[s] all private companies exactly the same” does not discriminate against interstate commerce. See *United Haulers Ass’n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 342 (2007). The Ninth Circuit has further found that a state law ban that treats all entities the

same and prohibits an item regardless of its origin is not discriminatory. *See Chinatown Neighborhood Ass'n v. Harris*, 794 F.3d 1136, 1146 (9th Cir. 2015) (finding a law banning the possession and sale of shark fins in California was not discriminatory where out-of-state shark fins would not be able to be sold in California); *See also Ass'n des Eleveurs de Canards et d'Oies due Quebec v. Harris*, 729 F.3d 937, 948 (9th Cir. 2013) (finding a law banning the sale of a product that was “the result of force feeding birds” was not discriminatory when the ban applied to both intrastate and interstate products).

Plaintiffs have not alleged facts sufficient to demonstrate that S.B. 793 is discriminatory on its face, in its purpose, or in its practical effects. The text of S.B. 793 does not expressly discriminate against out-of-state entities, as it only regulates the actions of retailers in California. *See* Cal. Health & Safety Code § 104559.5. Additionally, the purpose of S.B. 793 was to promote the health and safety of California residents, not discriminate against out-of-state entities.

Plaintiffs' opposition argues that the practical effects of S.B. 793 “fall almost entirely on out-of-state entities” because the majority of flavored tobacco products are manufactured outside of California. [Doc. No. 34 at 5]. Specifically, Plaintiffs argue that S.B. 793 “tells out-of-state tobacco manufacturers that they may not add characterizing flavors to their tobacco products before distributing them for retail sale in one of the Nation’s largest markets.” [Doc. No. 34 at 5]. There is no such assertion in the language of S.B. 793. Manufacturers are only mentioned in S.B. 793 in reference to how retailers are to determine

whether a product constitutes a prohibited flavored tobacco product. *See* § 104559.5. Furthermore, the only discrimination alleged in the Complaint is that out-of-state Plaintiffs are harmed because the ban “severely restricts their ability to market and sell such products to customers in California.” [Doc. No. 1 at ¶ 52]. The Complaint does not assert that S.B. 793 attempts to treat any out-of-state entities differently from in-state entities. All manufacturers, regardless of geographic location, are now potentially restricted in the marketability and sale of flavored tobacco products. For these reasons, the Court does not find that S.B. 793 discriminates against out-of-state entities.

2. S.B. 793 Does Not Violate the Extraterritoriality Doctrine

A statute that “controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State’s authority and is invalid regardless of whether the statute’s extraterritorial reach was intended by the legislature.” *Healy*, 491 U.S. at 336. However, the extraterritoriality doctrine as applied in *Healy* extends only to price-fixing statutes. *See Ass’n des Eleveurs de Canards et d’Oies due Quebec*, 729 F.3d at 951 (finding *Healy* inapplicable where the state statute did not impose any prices for the banned products and did not tie in-state prices to out-of-state prices). Furthermore, even if a statute has “significant extraterritorial effects,” it does not violate the dormant Commerce Clause “when those effects result from the regulation of in-state conduct.” *Chinatown Neighborhood Ass’n*, 794 F.3d at 1145.

Plaintiffs argue that S.B. 793 violates the extraterritoriality doctrine because its practical effects fall solely on out-of-state entities. In oral argument, Plaintiffs cited *Healy* as a basis for its extraterritoriality argument, but *Healy* is inapplicable. S.B. 793 is not a price-fixing statute, as it does not impose any prices for flavored tobacco products or relate California prices to out-of-state prices for these products. Additionally, any significant extraterritorial effects of S.B. 793 would result from the regulation of conduct occurring only in California. S.B. 793 solely controls the actions of retailers located within California by preventing them from selling flavored tobacco products. S.B. 793 does not control the retail sales of these products in other states, nor does it control the ability of manufacturers in or outside of California to continue manufacturing flavored tobacco products. In fact, manufacturers are still permitted to manufacture flavored tobacco products in California.

Accordingly, the Court does not find that the extraterritoriality doctrine is implicated by S.B. 793, and Plaintiffs have not established that S.B. 793 is discriminatory on its face, in its purpose, or in its practical effect.

3. S.B. 793 Does Not Unduly Burden Out-of-State Entities

A nondiscriminatory state law may still be invalidated under the dormant Commerce Clause if it substantially burdens interstate commerce. *Nat'l Ass'n of Optometrists & Opticians LensCrafters, Inc. v. Brown*, 567 F.3d 521, 528 (9th Cir. 2009). “A Plaintiff must first show that the statute imposes a substantial

burden before the Court will determine if the benefits of the challenged law are illusory.” *Ass’n des Eleveurs de Canards et d’Oies du Quebec*, 729 F.3d at 951-52. Most statutes that impose a burden on interstate commerce do so because they are discriminatory. *Id.*

Plaintiffs make the conclusory allegation that the “ban imposes burdens on out of state commerce,” [Doc. No. 1 at ¶ 66], but they do not allege facts supporting this conclusion. In their opposition, Plaintiffs argue that out-of-state commerce is burdened by forcing out-of-state manufacturers to change their operations, with costs of “tens of billions of dollars.” [Doc. No. 34 at 13]. Even if the Court were to accept that S.B. 793 would cause financial loss to the tobacco industry, that burden alone is not excessive enough for the Court to find that the ban substantially burdens interstate commerce. *See Nat’l Ass’n of Optometrists*, 567 F.3d at 528 (declining to find a dormant Commerce Clause violation where the only burden identified was plaintiffs’ financial losses).

Plaintiffs’ argument that S.B. 793 unconstitutionally undermines the requirement for national uniform standards in the production of flavored tobacco products is unpersuasive. S.B. 793 does not impose any standard of manufacturing on tobacco products. It does not require manufacturers to grow or process their products in any particular manner that departs from any national uniform standard. Plaintiffs have not demonstrated how S.B. 793’s prohibition of the retail sale of flavored tobacco products within the State of California requires out-of-state manufacturers to change or depart in any way from nationally uniform standards of production of such products.

S.B. 793 does not set standards of manufacture or marketing contrary to federal national standards, it is California's decision to opt out of the market for those flavored tobacco products. The TCA expressly preserved to state authority the right to place restrictions on the retail sale of a tobacco product, including its sale altogether. *See Cnty. of Los Angeles*, 29 F.4th at 555 (“Congress allowed the federal government to set the standards regarding how a product would be manufactured and marketed, but has left states, localities, and tribal entities the ability to restrict or opt out of that market altogether.”). S.B. 793 does not unconstitutionally violate federal regulation of tobacco product manufacture.

Plaintiffs' argument, citing *Schollenberger v. Pennsylvania*, 171 U.S. 1, 25 (1898), that a state law that bans within its state the sale of federal taxed products is invalid is also not persuasive. Under the TCA provisions, Congress allows states to place restrictions, including bans, on the retail sale of federally taxed tobacco products within a state. California is not bound to furnish a market for flavored tobacco products even if by opting out of that market it lessens the revenue of the general government. *See Austin v. Tennessee*, 179 U.S. 343, 349, (1900) (affirming a Tennessee law making it a misdemeanor to sell cigarettes in Tennessee).

For these reasons, the Court does not find that an undue burden has been imposed by S.B. 793.³

³ Because S.B. 793 is not discriminatory and does not impose a significant burden on interstate commerce, the Court need not assess the benefits of the law and the availability of less-

B. Leave to Amend

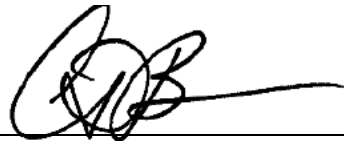
Plaintiffs ask the Court to grant leave to amend or stay this case until the Supreme Court issues a decision in *National Pork Producers Council v. Ross*, 6 F.4th 1021 (9th Cir. 2021). Leave to amend may be denied “if the proposed amendment either lacks merit or would not serve any purpose because to grant it would be futile in saving the plaintiff’s suit.” *Chinatown Neighborhood Ass’n*, 794 F.3d at 1144. The Court finds that any future amendment would be futile. The Court also declines to stay this case pending the decision in *National Pork*.

IV. CONCLUSION

Because Plaintiffs’ first claim of Preemption is barred by the Ninth Circuit’s decision in *County of Los Angeles*, Plaintiffs’ Preemption claim (Count One) is **DISMISSED as moot**. Because S.B. 793 does not discriminate against or impose an undue burden on interstate commerce, the Court finds that the Complaint has not stated a claim under the dormant Commerce Clause. Accordingly, Plaintiffs’ dormant Commerce Clause claim (Count Two) is **hereby DISMISSED with prejudice**.

It is **SO ORDERED**.

Dated: March 15, 2023



Hon. Cathy Ann Bencivengo
United States District Judge

burdensome alternatives. See *Chinatown Neighborhood Ass’n*, 76 F.3d at 1147.

APPENDIX C



**United States District Court
SOUTHERN DISTRICT OF CALIFORNIA**

(See Attachment)

Plaintiff,

V.

Robert Bonta, in his official capacity as Attorney General of California; Summer Stephan, in her official capacity as District Attorney for the County of San Diego

Defendant.

Civil Action No.
22cv1755-CAB-WVG

**JUDGMENT IN A
CIVIL CASE**

Decision by Court. This action came to trial or hearing before the Court. The issues have been tried or heard and a decision has been rendered.

IT IS HEREBY ORDERED AND ADJUDGED:

Because Plaintiffs' first claim of Preemption is barred by the Ninth Circuit's decision in County of Los Angeles, Plaintiffs' Preemption claim (Count One) is **DISMISSED** as moot. Because S.B. 793 does not

discriminate against or impose an undue burden on interstate commerce, the Court finds that the Complaint has not stated a claim under the dormant Commerce Clause. Accordingly, Plaintiffs' dormant Commerce Clause claim (Count Two) is hereby DISMISSED with prejudice.

Date: 3/15/23

**CLERK OF COURT JOHN
MORRILL, Clerk of Court**

By: s/ A. Hazard
A. Hazard, Deputy

**United States District Court
SOUTHERN DISTRICT OF CALIFORNIA
(ATTACHMENT)**

Civil Action No. 22cv1755-CAB-WVG

R. J. Reynolds Tobacco Company; R. J. Reynolds Vapor Company; American Snuff Company, LLC; Santa Fe Natural Tobacco Company, Inc.; Modoral Brands Inc; Neighborhood Market Association, Inc.; Morija, LLC doing business as Vapin the 619, Plaintiffs

APPENDIX D

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

R. J. REYNOLDS TOBACCO
COMPANY; et al.,

Plaintiffs-Appellants,

v.

ROB BONTA, in his official
capacity as Attorney General of
California; SUMMER STEPHAN,
in her official capacity as District
Attorney for the County of San
Diego,

Defendants-Appellees.

No. 22-56052

D.C. No.

3:22-cv-01755-

CAB-WVG

Southern District
of California,
San Diego

FILED

Jan 27, 2023

MOLLY C. DWYER,

Clerk

ORDER

Before: WARDLAW, CLIFTON, and SANCHEZ,
Circuit Judges.

The motion for summary affirmance (Docket Entry
No. 25) is granted. *See R.J. Reynolds Tobacco Co. v.*
County of Los Angeles, 29 F.4th 542 (9th Cir. 2022).

AFFIRMED.

APPENDIX E

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

R. J. REYNOLDS TOBACCO
COMPANY; et al.,

Plaintiffs-Appellants,

v.

ROB BONTA, in his official
capacity as Attorney General of
California; SUMMER STEPHAN,
in her official capacity as District
Attorney for the County of San
Diego,

Defendants-Appellees.

No. 22-56052

D.C. No.

3:22-cv-01755-

CAB-WVG

Southern District
of California,
San Diego

FILED

Nov 28, 2022

MOLLY C. DWYER,
Clerk

ORDER

Before: WARDLAW and W. FLETCHER, Circuit
Judges.

The emergency motion for injunction pending
appeal (Docket Entry No. 14) is denied. *See R.J.
Reynolds Tobacco Co. v. County of Los Angeles*, 29
F.4th 542 (9th Cir. 2022).

The existing briefing schedule remains in effect.

APPENDIX F

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

R.J. REYNOLDS
TOBACCO COMPANY, *et*
al.,

Plaintiffs,

v.

ROBERT BONTA, in his
official capacity as
Attorney General of
California; and SUMMER
STEPHAN, in her official
capacity as District
Attorney for the County of
San Diego,

Defendants.

Case No. 22-cv-01755-
CAB-WVG

Hon. Cathy Ann
Bencivengo

**ORDER DENYING
PLAINTIFFS’
MOTION FOR
PRELIMINARY
INJUNCTION AND
INJUNCTION
PENDING APPEAL
AND GRANTING
THE PARTIES’
JOINT MOTION TO
VACATE THE
BRIEFING
SCHEDULE**

[Doc. Nos. 13, 18]

In this matter, Plaintiffs ask the Court to declare that California Senate Bill 793 (“S.B. 793”) is invalid and unenforceable. Plaintiffs moved for a preliminary injunction and an injunction pending appeal on enforcement of S.B. 793 based on their express

preemption claim. [Doc. No. 13.] Plaintiffs acquiesced in the denial of that motion because, at this time, their express preemption claim is foreclosed in this Court by Ninth Circuit precedent. [Doc No. 13-1 (citing *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, 29 F.4th 542 (9th Cir. 2022), *cert. pending*, No. 22-338 (U.S. filed Oct. 7, 2022)).] Plaintiffs preserved their claim and their requests for injunctive relief for appeal. Defendants oppose Plaintiffs' motion.

Upon review of the record, the Court finds that the Ninth Circuit's decision in *County of Los Angeles* currently forecloses Plaintiffs' express preemption claim in this Court. This Court therefore must deny the motion for a preliminary injunction and an injunction pending appeal. Plaintiffs have nevertheless preserved their claim and Defendants have preserved their defenses and arguments for further appellate review.

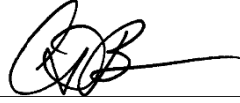
The parties have also jointly moved to vacate the briefing schedule on Plaintiffs' motion for a preliminary injunction and an injunction pending appeal.

Accordingly, the joint motion to vacate the briefing schedule on Plaintiffs' motion for a preliminary injunction and an injunction pending appeal [Doc. No. 18] is **GRANTED**, and Plaintiffs' motion for a preliminary injunction and an injunction pending appeal [Doc. No. 13] is **DENIED**.

IT IS SO ORDERED.

Dated: November 15, 2022

20a

A handwritten signature in black ink, appearing to be 'CAB', with a long horizontal stroke extending to the right.

Hon. Cathy Ann Bencivengo
United States District Judge

APPENDIX G

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*[Additional counsel identified on signature page]
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R.J. Reynolds Tobacco Company; R.J. Reynolds Vapor Company; American Snuff Company, LLC; Santa Fe Natural Tobacco Company, Inc.; Modoral Brands Inc.; Neighborhood Market Association, Inc.; and Morija, LLC dba Vapin' the 619

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

R. J. REYNOLDS
TOBACCO COMPANY,
et al.,

Plaintiffs,

v.

ROBERT BONTA, in his
official capacity as
Attorney General of
California; and SUMMER
STEPHAN, in her official
capacity as District

Case No. 3:22-cv-01755-
BEN-MSB

Hon. Roger T. Benitez

**NOTICE OF MOTION
AND PLAINTIFFS'
MOTION FOR
PRELIMINARY
INJUNCTION AND
INJUNCTION
PENDING APPEAL**

Attorney for the County of San Diego, <i>Defendants.</i>	Hearing Date: December 12, 2022 Time: 10:30 A.M. Courtroom: 5A Complaint Filed: November 9, 2022
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TO ALL PARTIES AND TO THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that, Plaintiffs R.J. Reynolds Tobacco Company; R.J. Reynolds Vapor Company; American Snuff Company, LLC; Santa Fe Natural Tobacco Company, Inc.; Modoral Brands Inc.; Neighborhood Market Association, Inc.; and Morija, LLC dba Vapin' the 619 will and hereby do move this Court, under Federal Rule of Civil Procedure 65, for the issuance of a preliminary injunction on the First Claim for Relief of Plaintiffs' Complaint (express preemption). ECF No. 1. Plaintiffs seek a preliminary injunction enjoining Defendants from implementing or enforcing California Senate Bill 793's ("SB793") prohibition on flavored tobacco products, which was signed into law on August 28, 2020, suspended by referendum, approved by referendum on November 8, 2022, and which will take effect no later than December 21, 2022.

Plaintiffs further will and hereby do move for an injunction pending appeal of this Court's inevitable denial of the motion for a preliminary injunction. *See* Fed. R. App. Proc. 8(a).

Plaintiffs recognize that, at this time, their express preemption claim is foreclosed in this Court under Ninth Circuit precedent and that this Court therefore

must deny the motion for a preliminary injunction and the motion for an injunction pending appeal. *See R.J. Reynolds Tobacco Co. v. County of Los Angeles*, 29 F.4th 542 (9th Cir. 2022) (“*Los Angeles County*”), *cert. pending*, No. 22-338 (U.S. filed Oct. 7, 2022). Nonetheless, Plaintiffs believe that *Los Angeles County* was wrongly decided and the plaintiffs in *Los Angeles County* (which include some of the Plaintiffs in this case) have sought Supreme Court review. Plaintiffs in this case preserve (for appellate review) their claim that the Tobacco Control Act expressly preempts California’s SB793 and wish to seek relief from a higher court as quickly as possible.

This Motion is based on this Notice of Motion, the concurrently filed Memorandum of Points and Authorities, the declarations submitted, and the pleadings and papers on file in this action. Given that SB793 will go into effect no later than December 21, 2022, Plaintiffs request that this Court rule expeditiously on this motion, but no later than November 23, 2022. In a concurrently submitted unopposed ex parte application, Plaintiffs have also requested that this Court shorten the briefing schedule so that Plaintiffs may timely seek relief in a higher court. In particular, Plaintiffs propose that any opposition be filed by November 17, 2022 and any reply be filed by 2 days from the opposition’s filing.

Dated: November 10, 2022

Respectfully submitted,

JONES DAY

24a

By: /s/ Steven N. Geise

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COMPANY; AMERICAN

SNUFF COMPANY, LLC;

SANTA FE NATURAL

TOBACCO COMPANY,

INC.; MODORAL BRANDS

INC.; NEIGHBORHOOD

MARKET ASSOCIATION,

INC.; and MORIJA, LLC

dba VAPIN' THE 619

APPENDIX H

**Federal Food, Drug, and Cosmetic Act § 301
21 U.S.C. § 331
Prohibited acts**

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 350d, 355, or 360bbb-3 of this title.

(e) The refusal to permit access to or copying of any record as required by section 350a, 350c, 350f(j), 350e, 354, 360bbb-3, 373, 374(a), 379aa, or 379aa-1 of this title; or the failure to establish or maintain any record, or make any report, required under section 350a, 350c(b), 350f, 350e, 354, 355(i) or (k), 360b(a)(4)(C), 360b(j), (l) or (m), 360ccc-1(i), 360e(f), 360i, 360bbb-3, 379aa, 379aa-1, 387i, or 387t of this title or the refusal to permit access to or verification

or copying of any such required record; or the violation of any recordkeeping requirement under section 2223 of this title (except when such violation is committed by a farm).

(f) The refusal to permit entry or inspection as authorized by section 374 of this title.

(g) The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 333(c)(2) of this title, which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, tobacco product, or cosmetic; or the giving of a guaranty or undertaking referred to in section 333(c)(3) of this title, which guaranty or undertaking is false.

(i)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 344 or 379e of this title.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing

upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of section 344, 348, 350a, 350c, 355, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 360ccc, 360ccc-1, 360ccc-2, 374, 379, 379e, 387d, 387e, 387f, 387g, 387h, 387i, or 387t(b) of this title concerning any method or process which as a trade secret is entitled to protection; or the violating of section 346a(i)(2) of this title or any regulation issued under that section..⁴ This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after

⁴ So in original.

shipment in interstate commerce and results in such article being adulterated or misbranded.

(l) Repealed. Pub.L. 105-115, Title IV, § 421, Nov. 21, 1997, 111 Stat. 2380.

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of subsections (b) or (c) of section 347 of this title.

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 374 of this title.

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter.

(p) The failure to register in accordance with section 360 or 387e of this title, the failure to provide any information required by section 360(j), 360(k), 387e(i), or 387e(j) of this title, or the failure to provide a notice required by section 360(j)(2) or 387e(i)(3) of this title.

(q)(1) The failure or refusal—

(A) to comply with any requirement prescribed under section 360h, 360j(g), 387c(b), 387g, 387h, or 387o of this title;

(B) to furnish any notification or other material or information required by or under section 360i, 360j(g), 387d, 387i, or 387t of this title; or

(C) to comply with a requirement under section 360l or 387m of this title.

(2) With respect to any device or tobacco product, the submission of any report that is required by or under this chapter that is false or misleading in any material respect.

(r) The movement of a device, drug, or tobacco product in violation of an order under section 334(g) of this title or the removal or alteration of any mark or label required by the order to identify the device, drug, or tobacco product as detained.

(s) The failure to provide the notice required by section 350a(c) or 350a(e) of this title, the failure to make the reports required by section 350a(f)(1)(B) of this title, the failure to retain the records required by section 350a(b)(4) of this title, or the failure to meet the requirements prescribed under section 350a(f)(3) of this title.

(t) The importation of a drug in violation of section 381(d)(1) of this title, the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 353(c) of this title, the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the

counterfeiting of such a coupon in violation of section 353(c)(2) of this title, the distribution of a drug sample in violation of section 353(d) of this title or the failure to otherwise comply with the requirements of section 353(d) of this title, the distribution of drugs in violation of section 353(e) of this title, failure to comply with the requirements under section 360eee-1 of this title, the failure to comply with the requirements under section 360eee-3 of this title, as applicable, or the failure to otherwise comply with the requirements of section 353(e) of this title.

(u) The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under section 360b(a)(4)(A), 360b(a)(4)(D), or 360b(a)(5) of this title.

(v) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 350b of this title.

(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 381(d)(3) of this title; the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 381(e) or 382 of this title, or with section 262(h) of Title 42; or the failure to so export or to destroy such

an article or portions thereof, or such a finished product.

(x) The falsification of a declaration of conformity submitted under section 360d(c) of this title or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section.

(y) In the case of a drug, device, or food—

(1) the submission of a report or recommendation by a person accredited under section 360m of this title that is false or misleading in any material respect;

(2) the disclosure by a person accredited under section 360m of this title of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

(3) the receipt by a person accredited under section 360m of this title of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this chapter.

(z) Omitted

(aa) The importation of a prescription drug in violation of section 384 of this title, the falsification of any record required to be maintained or provided to the Secretary under such section, or any other violation of regulations under such section.

(bb) The transfer of an article of food in violation of an order under section 334(h) of this title, or the

removal or alteration of any mark or label required by the order to identify the article as detained.

(cc) The importing or offering for import into the United States of an article of food or a drug by, with the assistance of, or at the direction of, a person debarred from such activity under section 335a(b)(3) of this title.

(dd) The failure to register in accordance with section 350d of this title.

(ee) The importing or offering for import into the United States of an article of food in violation of the requirements under section 381(m) of this title.

(ff) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under section 381(o) of this title.

(gg) The knowing failure to comply with paragraph (7)(E) of section 374(g) of this title; the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.

(hh) The failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the sanitary transportation practices prescribed by the Secretary under section 350e of this title.

(ii) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 379aa or 379aa-1 of this title)

or the falsification of a serious adverse event report (as defined under section 379aa or 379aa-1 of this title) submitted to the Secretary.

(jj)(1) The failure to submit the certification required by section 282(j)(5)(B) of Title 42, or knowingly submitting a false certification under such section.

(2) The failure to submit clinical trial information required under subsection (j) of section 282 of Title 42.

(3) The submission of clinical trial information under subsection (j) of section 282 of Title 42 that is false or misleading in any particular under paragraph (5)(D) of such subsection (j).

(kk) The dissemination of a television advertisement without complying with section 353c of this title.

(ll) The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 355 of this title, a biological product licensed under section 262 of Title 42, or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless—

(1) such drug or such biological product was marketed in food before any approval of the drug under section 355 of this title, before licensure of the biological product under such section 262 of Title 42, and before any substantial clinical investigations involving the drug or the biological product have been instituted;

(2) the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food;

(3) the use of the drug or the biological product in the food is to enhance the safety of the food to which the drug or the biological product is added or applied and not to have independent biological or therapeutic effects on humans, and the use is in conformity with—

(A) a regulation issued under section 348 of this title prescribing conditions of safe use in food;

(B) a regulation listing or affirming conditions under which the use of the drug or the biological product in food is generally recognized as safe;

(C) the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier's determination that the use of the drug or the biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier;

(D) a food contact substance notification that is effective under section 348(h) of this title; or

(E) such drug or biological product had been marketed for smoking cessation prior to September 27, 2007; or

(4) the drug is a new animal drug whose use is not unsafe under section 360b of this title.

(mm) The failure to submit a report or provide a notification required under section 350f(d) of this title.

(nn) The falsification of a report or notification required under section 350f(d) of this title.

(oo) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 333(f) of this title.

(pp) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 387k of this title.

(qq)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

(rr) The charitable distribution of tobacco products.

(ss) The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.

(tt) Making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that

(1) the product is approved by the Food and Drug Administration;

(2) the Food and Drug Administration deems the product to be safe for use by consumers;

(3) the product is endorsed by the Food and Drug Administration for use by consumers; or

(4) the product is safe or less harmful by virtue of—

(A) its regulation or inspection by the Food and Drug Administration; or

(B) its compliance with regulatory requirements set by the Food and Drug Administration;

including any such statement or representation rendering the product misbranded under section 387c of this title.

(uu) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or

agent in charge of such facility is not in compliance with section 350g of this title.

(vv) The failure to comply with the requirements under section 350h of this title.

(ww) The failure to comply with section 350i of this title.

(xx) The refusal or failure to follow an order under section 350l of this title.

(yy) The knowing and willful failure to comply with the notification requirement under section 350f(h) of this title.

(zz) The importation or offering for importation of a food if the importer (as defined in section 384a of this title) does not have in place a foreign supplier verification program in compliance with such section 384a of this title.

(aaa) The failure to register in accordance with section 381(s) of this title.

(bbb) The failure to notify the Secretary in violation of section 360bbb-7 of this title.

(ccc)(1) The resale of a compounded drug that is labeled “not for resale” in accordance with section 353b of this title.

(2) With respect to a drug to be compounded pursuant to section 353a or 353b of this title, the intentional falsification of a prescription, as applicable.

(3) The failure to report drugs or adverse events by an entity that is registered in accordance with subsection (b) of section 353b of this title.

(ddd)(1) The manufacture or the introduction or delivery for introduction into interstate commerce of a rinse-off cosmetic that contains intentionally-added plastic microbeads.

(2) In this paragraph—

(A) the term “plastic microbead” means any solid plastic particle that is less than five millimeters in size and is intended to be used to exfoliate or cleanse the human body or any part thereof; and

(B) the term “rinse-off cosmetic” includes toothpaste.

(eee) The failure to comply with any order issued under section 360bbb-8d of this title.

Federal Food, Drug, and Cosmetic Act § 900
21 U.S.C. § 387
Definitions

In this subchapter:

(1) Additive

The term “additive” means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

(2) Brand

The term “brand” means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name, identifiable pattern of colors, or any combination of such attributes.

(3) Cigarette

The term “cigarette”—

(A) means a product that—

(i) is a tobacco product; and

(ii) meets the definition of the term “cigarette” in section 1332(1) of Title 15; and

(B) includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler,

or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

(4) Cigarette tobacco

The term “cigarette tobacco” means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this subchapter shall also apply to cigarette tobacco.

(5) Commerce

The term “commerce” has the meaning given that term by section 1332(2) of Title 15.

(6) Counterfeit tobacco product

The term “counterfeit tobacco product” means a tobacco product (or the container or labeling of such a product) that, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a tobacco product listed in a registration under section 387e(i)(1) of this title.

(7) Distributor

The term “distributor” as regards a tobacco product means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for purposes of this subchapter.

(8) Illicit trade

The term “illicit trade” means any practice or conduct prohibited by law which relates to production, shipment, receipt, possession, distribution, sale, or purchase of tobacco products including any practice or conduct intended to facilitate such activity.

(9) Indian country

The term “Indian country” has the meaning given such term in section 1151 of Title 18.

(10) Indian tribe

The term “Indian tribe” has the meaning given such term in section 5304(e) of Title 25.

(11) Little cigar

The term “little cigar” means a product that—

(A) is a tobacco product; and

(B) meets the definition of the term “little cigar” in section 1332(7) of Title 15.

(12) Nicotine

The term “nicotine” means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.

(13) Package

The term “package” means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

(14) Retailer

The term “retailer” means any person, government, or entity who sells tobacco products to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted.

(15) Roll-your-own tobacco

The term “roll-your-own tobacco” means any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

(16) Small tobacco product manufacturer

The term “small tobacco product manufacturer” means a tobacco product manufacturer that employs fewer than 350 employees. For purposes of determining the number of employees of a manufacturer under the preceding sentence, the employees of a manufacturer are deemed to include the employees of each entity that controls, is controlled by, or is under common control with such manufacturer.

(17) Smoke constituent

The term “smoke constituent” means any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the cigarette to the smoke or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product.

(18) Smokeless tobacco

The term “smokeless tobacco” means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

(19) State; Territory

The terms “State” and “Territory” shall have the meanings given to such terms in section 321 of this title.

(20) Tobacco product manufacturer

The term “tobacco product manufacturer” means any person, including any repacker or relabeler, who—

(A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or

(B) imports a finished tobacco product for sale or distribution in the United States.

(21) Tobacco warehouse

(A) Subject to subparagraphs (B) and (C), the term “tobacco warehouse” includes any person—

(i) who—

(I) removes foreign material from tobacco leaf through nothing other than a mechanical process;

(II) humidifies tobacco leaf with nothing other than potable water in the form of steam or mist; or

(III) de-stems, dries, and packs tobacco leaf for storage and shipment;

(ii) who performs no other actions with respect to tobacco leaf; and

(iii) who provides to any manufacturer to whom the person sells tobacco all information related to the person's actions described in clause (i) that is necessary for compliance with this chapter.

(B) The term "tobacco warehouse" excludes any person who—

(i) reconstitutes tobacco leaf;

(ii) is a manufacturer, distributor, or retailer of a tobacco product; or

(iii) applies any chemical, additive, or substance to the tobacco leaf other than potable water in the form of steam or mist.

(C) The definition of the term "tobacco warehouse" in subparagraph (A) shall not apply to the extent to which the Secretary determines, through rulemaking, that regulation under this subchapter of the actions described in such subparagraph is appropriate for the protection of the public health.

(22) United States

The term "United States" means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

Federal Food, Drug, and Cosmetic Act § 901
21 U.S.C. § 387a
FDA authority over tobacco products

(a) In general

Tobacco products, including modified risk tobacco products for which an order has been issued in accordance with section 387k of this title, shall be regulated by the Secretary under this subchapter and shall not be subject to the provisions of subchapter V.

(b) Applicability

This subchapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter.

(c) Scope

(1) In general

Nothing in this subchapter, or any policy issued or regulation promulgated thereunder, or in sections 101(a), 102, or 103 of Title I, Title II, or Title III of the Family Smoking Prevention and Tobacco Control Act, shall be construed to affect, expand, or limit the Secretary's authority over (including the authority to determine whether products may be regulated), or the regulation of, products under this chapter that are not tobacco products under subchapter V or any other subchapter.

(2) Limitation of authority

(A) In general

The provisions of this subchapter shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the

producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

(B) Exception

Notwithstanding subparagraph (A), if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this subchapter in the producer's capacity as a manufacturer. The exception in this subparagraph shall not apply to a producer of tobacco leaf who grows tobacco under a contract with a tobacco product manufacturer and who is not otherwise engaged in the manufacturing process.

(C) Rule of construction

Nothing in this subchapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer affecting production.

(d) Rulemaking procedures

Each rulemaking under this subchapter shall be in accordance with chapter 5 of Title 5. This subsection shall not be construed to affect the rulemaking provisions of section 102(a) of the Family Smoking Prevention and Tobacco Control Act.

(e) Center for Tobacco Products

Not later than 90 days after June 22, 2009, the Secretary shall establish within the Food and Drug Administration the Center for Tobacco Products, which shall report to the Commissioner of Food and Drugs in the same manner as the other agency centers within the Food and Drug Administration. The Center shall be responsible for the implementation of this subchapter and related matters assigned by the Commissioner.

(f) Office to assist small tobacco product manufacturers

The Secretary shall establish within the Food and Drug Administration an identifiable office to provide technical and other nonfinancial assistance to small tobacco product manufacturers to assist them in complying with the requirements of this chapter.

(g) Consultation prior to rulemaking

Prior to promulgating rules under this subchapter, the Secretary shall endeavor to consult with other Federal agencies as appropriate.

Federal Food, Drug, and Cosmetic Act § 902
21 U.S.C. § 387b
Adulterated tobacco products

A tobacco product shall be deemed to be adulterated if—

(1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health;

(2) it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;

(3) its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(4) the manufacturer or importer of the tobacco product fails to pay a user fee assessed to such manufacturer or importer pursuant to section 387s of this title by the date specified in section 387s of this title or by the 30th day after final agency action on a resolution of any dispute as to the amount of such fee;

(5) it is, or purports to be or is represented as, a tobacco product which is subject to a tobacco product standard established under section 387g of this title unless such tobacco product is in all respects in conformity with such standard;

(6)(A) it is required by section 387j(a) of this title to have premarket review and does not have an

order in effect under section 387j(c)(1)(A)(i) of this title; or

(B) it is in violation of an order under section 387j(c)(1)(A) of this title;

(7) the methods used in, or the facilities or controls used for, its manufacture, packing, or storage are not in conformity with applicable requirements under section 387f(e)(1) of this title or an applicable condition prescribed by an order under section 387f(e)(2) of this title; or

(8) it is in violation of section 387k of this title.

Federal Food, Drug, and Cosmetic Act § 907
21 U.S.C. § 387g
Tobacco product standards

(a) In general

(1) Special rules

(A) Special rule for cigarettes

Beginning 3 months after June 22, 2009, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this chapter applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.

(B) Additional special rule

Beginning 2 years after June 22, 2009, a tobacco product manufacturer shall not use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco.

(2) Revision of tobacco product standards

The Secretary may revise the tobacco product standards in paragraph (1) in accordance with subsection (c).

(3) Tobacco product standards

(A) In general

The Secretary may adopt tobacco product standards in addition to those in paragraph (1) if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health.

(B) Determinations

(i) Considerations

In making a finding described in subparagraph (A), the Secretary shall consider scientific evidence concerning—

(I) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;

(II) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(III) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

(ii) Additional considerations

In the event that the Secretary makes a determination, set forth in a proposed tobacco product standard in a proposed rule, that it is appropriate for the protection of public health

to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a tobacco product because the Secretary has found that the additive, constituent, or other component is or may be harmful, any party objecting to the proposed standard on the ground that the proposed standard will not reduce or eliminate the risk of illness or injury may provide for the Secretary's consideration scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury.

(4) Content of tobacco product standards

A tobacco product standard established under this section for a tobacco product—

(A) shall include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—

- (i)** for nicotine yields of the product;
- (ii)** for the reduction or elimination of other constituents, including smoke constituents, or harmful components of the product; or
- (iii)** relating to any other requirement under subparagraph (B);

(B) shall, where appropriate for the protection of the public health, include—

- (i)** provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product;
- (ii)** provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product;

(iii) provisions for the measurement of the tobacco product characteristics of the tobacco product;

(iv) provisions requiring that the results of each or of certain of the tests of the tobacco product required to be made under clause (ii) show that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and

(v) a provision requiring that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 387f(d) of this title;

(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper use of the tobacco product; and

(D) shall require tobacco products containing foreign-grown tobacco to meet the same standards applicable to tobacco products containing domestically grown tobacco.

(5) Periodic reevaluation of tobacco product standards

The Secretary shall provide for periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data. The Secretary may provide for testing under paragraph (4)(B) by any person.

(6) Involvement of other agencies; informed persons

In carrying out duties under this section, the Secretary shall endeavor to—

- (A) use personnel, facilities, and other technical support available in other Federal agencies;
- (B) consult with other Federal agencies concerned with standard setting and other nationally or internationally recognized standard-setting entities; and
- (C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, agricultural, or consumer organizations who in the Secretary's judgment can make a significant contribution.

(b) Considerations by Secretary

(1) Technical achievability

The Secretary shall consider information submitted in connection with a proposed standard regarding the technical achievability of compliance with such standard.

(2) Other considerations

The Secretary shall consider all other information submitted in connection with a proposed standard, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this subchapter and the significance of such demand.

(c) Proposed standards**(1) In general**

The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any tobacco product standard.

(2) Requirements of notice

A notice of proposed rulemaking for the establishment or amendment of a tobacco product standard for a tobacco product shall—

(A) set forth a finding with supporting justification that the tobacco product standard is appropriate for the protection of the public health;

(B) invite interested persons to submit a draft or proposed tobacco product standard for consideration by the Secretary;

(C) invite interested persons to submit comments on structuring the standard so that it does not advantage foreign-grown tobacco over domestically grown tobacco; and

(D) invite the Secretary of Agriculture to provide any information or analysis which the Secretary of Agriculture believes is relevant to the proposed tobacco product standard.

(3) Finding

A notice of proposed rulemaking for the revocation of a tobacco product standard shall set forth a finding with supporting justification that the tobacco product standard is no longer appropriate for the protection of the public health.

(4) Comment

The Secretary shall provide for a comment period of not less than 60 days.

(d) Promulgation**(1) In general**

After the expiration of the period for comment on a notice of proposed rulemaking published under subsection (c) respecting a tobacco product standard and after consideration of comments submitted under subsections (b) and (c) and any report from the Tobacco Products Scientific Advisory Committee, the Secretary shall—

(A) if the Secretary determines that the standard would be appropriate for the protection of the public health, promulgate a regulation establishing a tobacco product standard and publish in the Federal Register findings on the matters referred to in subsection (c); or

(B) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

(2) Effective date

A regulation establishing a tobacco product standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade. In establishing

such effective date or dates, the Secretary shall consider information submitted in connection with a proposed product standard by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with the standard, and including information concerning the existence of patents that make it impossible to comply in the timeframe envisioned in the proposed standard. If the Secretary determines, based on the Secretary's evaluation of submitted comments, that a product standard can be met only by manufacturers requiring substantial changes to the methods of farming the domestically grown tobacco used by the manufacturer, the effective date of that product standard shall be not less than 2 years after the date of publication of the final regulation establishing the standard.

(3) Limitation on power granted to the Food and Drug Administration

Because of the importance of a decision of the Secretary to issue a regulation—

(A) banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products; or

(B) requiring the reduction of nicotine yields of a tobacco product to zero, the Secretary is prohibited from taking such actions under this chapter.

(4) Amendment; revocation

(A) Authority

The Secretary, upon the Secretary's own initiative or upon petition of an interested person,

may by a regulation, promulgated in accordance with the requirements of subsection (c) and paragraph (2), amend or revoke a tobacco product standard.

(B) Effective date

The Secretary may declare a proposed amendment of a tobacco product standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if the Secretary determines that making it so effective is in the public interest.

(5) Referral to Advisory Committee

(A) In general

The Secretary may refer a proposed regulation for the establishment, amendment, or revocation of a tobacco product standard to the Tobacco Products Scientific Advisory Committee for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment.

(B) Initiation of referral

The Secretary may make a referral under this paragraph—

- (i)** on the Secretary's own initiative; or
- (ii)** upon the request of an interested person that—

(I) demonstrates good cause for the referral; and

(II) is made before the expiration of the period for submission of comments on the proposed regulation.

(C) Provision of data

If a proposed regulation is referred under this paragraph to the Tobacco Products Scientific Advisory Committee, the Secretary shall provide the Advisory Committee with the data and information on which such proposed regulation is based.

(D) Report and recommendation

The Tobacco Products Scientific Advisory Committee shall, within 60 days after the referral of a proposed regulation under this paragraph and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation.

(E) Public availability

The Secretary shall make a copy of each report and recommendation under subparagraph (D) publicly available.

(e) Menthol cigarettes**(1) Referral; considerations**

Immediately upon the establishment of the Tobacco Products Scientific Advisory Committee under section 387q(a) of this title, the Secretary shall refer to the Committee for report and recommendation, under section 387q(c)(4) of this title, the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities. In its review, the Tobacco Products Scientific Advisory Committee shall

address the considerations listed in subsections (a)(3)(B)(i) and (b).

(2) Report and recommendation

Not later than 1 year after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required pursuant to paragraph (1).

(3) Rule of construction

Nothing in this subsection shall be construed to limit the Secretary's authority to take action under this section or other sections of this chapter applicable to menthol.

(f) Dissolvable tobacco products

(1) Referral; considerations

The Secretary shall refer to the Tobacco Products Scientific Advisory Committee for report and recommendation, under section 387q(c)(4) of this title, the issue of the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsection (a)(3)(B)(i).

(2) Report and recommendation

Not later than 2 years after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required pursuant to paragraph (1).

(3) Rule of construction

Nothing in this subsection shall be construed to limit the Secretary's authority to take action under this section or other sections of this chapter at any time applicable to any dissolvable tobacco product.

Federal Food, Drug, and Cosmetic Act § 910
21 U.S.C. § 387j
Application for review of certain
tobacco products

(a) In general

(1) New tobacco product defined

For purposes of this section the term “new tobacco product” means—

(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

(2) Premarket review required

(A) New products

An order under subsection (c)(1)(A)(i) for a new tobacco product is required unless—

(i) the manufacturer has submitted a report under section 387e(j) of this title; and the Secretary has issued an order that the tobacco product—

(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; and

(II) is in compliance with the requirements of this chapter; or

(ii) the tobacco product is exempt from the requirements of section 387e(j) of this title pursuant to a regulation issued under section 387e(j)(3) of this title.

(B) Application to certain post-February 15, 2007, products

Subparagraph (A) shall not apply to a tobacco product—

(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after June 22, 2009; and

(ii) for which a report was submitted under section 387e(j) of this title within such 21-month period, except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

(3) Substantially equivalent defined

(A) In general

In this section and section 387e(j) of this title, the term “substantially equivalent” or “substantial equivalence” means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product—

(i) has the same characteristics as the predicate tobacco product; or

(ii) has different characteristics and the information submitted contains information,

including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

(B) Characteristics

In subparagraph (A), the term “characteristics” means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

(C) Limitation

A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

(4) Health information

(A) Summary

As part of a submission under section 387e(j) of this title respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request by any person.

(B) Required information

Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco

product is substantially equivalent to another tobacco product.

(b) Application

(1) Contents

An application under this section shall contain—

(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

(D) an identifying reference to any tobacco product standard under section 387g of this title which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

(F) specimens of the labeling proposed to be used for such tobacco product; and

(G) such other information relevant to the subject matter of the application as the Secretary may require.

(2) Referral to Tobacco Products Scientific Advisory Committee

Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

- (A) may, on the Secretary's own initiative; or
- (B) may, upon the request of an applicant, refer such application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Secretary may establish) of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

(c) Action on application

(1) Deadline

(A) In general

As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after considering the report and recommendation submitted under subsection (b)(2), shall—

- (i) issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Secretary finds that none of the grounds specified in paragraph (2) of this subsection applies; or
- (ii) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Secretary finds (and sets forth the basis for such finding as part

of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

(B) Restrictions on sale and distribution

An order under subparagraph (A)(i) may require that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 387f(d) of this title.

(2) Denial of application

The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 387f(e) of this title;

(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 387g of this title, and there is a lack of adequate information to justify the deviation from such standard.

(3) Denial information

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to remove such application from deniable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

(4) Basis for finding

For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

(5) Basis for action**(A) Investigations**

For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by

training and experience to evaluate the tobacco product.

(B) Other evidence

If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product, the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

(d) Withdrawal and temporary suspension

(1) In general

The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee, and after due notice and opportunity for informal hearing for a tobacco product for which an order was issued under subsection (c)(1)(A)(i), issue an order withdrawing the order if the Secretary finds—

(A) that the continued marketing of such tobacco product no longer is appropriate for the protection of the public health;

(B) that the application contained or was accompanied by an untrue statement of a material fact;

(C) that the applicant—

(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 387i of this title;

(ii) has refused to permit access to, or copying or verification of, such records as required by section 374 of this title; or

(iii) has not complied with the requirements of section 387e of this title;

(D) on the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 387f(e) of this title and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

(E) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was reviewed, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

(F) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such order was issued, that such tobacco product is not shown to conform in all respects to a tobacco product standard which is in effect under section 387g of this title, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard.

(2) Appeal

The holder of an application subject to an order issued under paragraph (1) withdrawing an order issued pursuant to subsection (c)(1)(A)(i) may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with section 387l of this title.

(3) Temporary suspension

If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco product under an order would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market, the Secretary shall by order temporarily suspend the authority of the manufacturer to market the product. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

(e) Service of order

An order issued by the Secretary under this section shall be served—

- (1) in person by any officer or employee of the department designated by the Secretary; or
- (2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Secretary.

(f) Records

(1) Additional information

In the case of any tobacco product for which an order issued pursuant to subsection (c)(1)(A)(i) for an application filed under subsection (b) is in effect, the

applicant shall establish and maintain such records, and make such reports to the Secretary, as the Secretary may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending such order.

(2) Access to records

Each person required under this section to maintain records, and each person in charge of custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(g) Investigational tobacco product exemption for investigational use

The Secretary may exempt tobacco products intended for investigational use from the provisions of this subchapter under such conditions as the Secretary may by regulation prescribe.

**Federal Food, Drug, and Cosmetic Act § 916
21 U.S.C. § 387p**

Preservation of State and local authority

(a) In general

(1) Preservation

Except as provided in paragraph (2)(A), nothing in this subchapter, or rules promulgated under this subchapter, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this subchapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products. No provision of this subchapter shall limit or otherwise affect any State, tribal, or local taxation of tobacco products.

(2) Preemption of certain State and local requirements

(A) In general

No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration,

good manufacturing standards, or modified risk tobacco products.

(B) Exception

Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products. Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 552(b)(4) of Title 5 shall be treated as a trade secret and confidential information by the State.

(b) Rule of construction regarding product liability

No provision of this subchapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.



75a

Senate Bill No. 793
CHAPTER 34

An act to add Article 5 (commencing with Section 104559.5) to Chapter 1 of Part 3 of Division 103 of the Health and Safety Code, relating to tobacco products.

[Approved by Governor August 28, 2020. Filed with Secretary of State August 28, 2020.]

LEGISLATIVE COUNSEL'S DIGEST

SB 793, Hill. Flavored tobacco products.

Existing law, the Stop Tobacco Access to Kids Enforcement (STAKE) Act, prohibits a person from selling or otherwise furnishing tobacco products, as defined, to a person under 21 years of age. Existing law also prohibits the use of tobacco products in county offices of education, on charter school or school district property, or near a playground or youth sports event, as specified.

This bill would prohibit a tobacco retailer, or any of the tobacco retailer's agents or employees, from selling, offering for sale, or possessing with the intent to sell or offer for sale, a flavored tobacco product or a tobacco product flavor enhancer, as those terms are defined, except as specified. The bill would make a violation of this prohibition an infraction punishable by a fine of \$250 for each violation. The bill would state the intent of the Legislature that these provisions do not preempt or prohibit the adoption and implementation of local ordinances that impose greater restrictions on the access to tobacco products than the restrictions imposed by the bill, as specified. The bill would state that its provisions are severable. By creating a new crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Article 5 (commencing with Section 104559.5) is added to Chapter 1 of Part 3 of Division 103 of the Health and Safety Code, to read:

Article 5. Tobacco Sale Prohibition

104559.5. (a) For purposes of this section, the following definitions apply:

(1) "Characterizing flavor" means a distinguishable taste or aroma, or both, other than the taste or aroma of tobacco, imparted by a tobacco product or any byproduct produced by the tobacco product. Characterizing flavors include, but are not limited to, tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, menthol, mint, wintergreen, herb, or spice. A tobacco product shall not be determined to have a characterizing flavor solely because of the use of additives or flavorings or the provision of ingredient information. Rather, it is the presence of a distinguishable taste or aroma, or both, as described in the first sentence of this definition, that constitutes a characterizing flavor.

(2) "Constituent" means any ingredient, substance, chemical, or compound, other than tobacco, water, or

reconstituted tobacco sheet, that is added by the manufacturer to a tobacco product during the processing, manufacture, or packing of the tobacco product.

(3) “Flavored shisha tobacco product” means any shisha tobacco product that contains a constituent that imparts a characterizing flavor.

(4) “Flavored tobacco product” means any tobacco product that contains a constituent that imparts a characterizing flavor.

(5) “Hookah” means a type of waterpipe, used to smoke shisha or other tobacco products, with a long flexible tube for drawing aerosol through water. Components of a hookah may include heads, stems, bowls, and hoses.

(6) “Hookah tobacco retailer” means a tobacco retailer that is engaged in the retail sale of shisha tobacco products, hookah, and hookah smoking accessories.

(7) “Labeling” means written, printed, pictorial, or graphic matter upon a tobacco product or any of its packaging.

(8) “Loose leaf tobacco” consists of cut or shredded pipe tobacco, usually sold in pouches, excluding any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes, including roll-your-own cigarettes.

(9) “Packaging” means a pack, box, carton, or container of any kind, or, if no other container, any

wrapping, including cellophane, in which a tobacco product is sold or offered for sale to a consumer.

(10) “Premium cigar” means any cigar that is handmade, is not mass produced by use of mechanization, has a wrapper that is made entirely from whole tobacco leaf, and has a wholesale price of no less than twelve dollars (\$12). A premium cigar does not have a filter, tip, or nontobacco mouthpiece and is capped by hand.

(11) “Retail location” means both of the following:

(A) A building from which tobacco products are sold at retail.

(B) A vending machine.

(12) “Sale” or “sold” means a sale as that term is defined in Section 30006 of the Revenue and Taxation Code.

(13) “Shisha tobacco product” means a tobacco product smoked or intended to be smoked in a hookah. “Shisha tobacco product” includes, and may be referred to as, hookah tobacco, waterpipe tobacco, maassel, narghile, and argileh. “Shisha tobacco product” does not include any electronic devices, such as an electronic hookah, electronic cigarette, or electronic tobacco product.

(14) “Tobacco product” means a tobacco product as defined in paragraph (8) of subdivision (a) of Section 104495, as that provision may be amended from time to time.

(15) “Tobacco product flavor enhancer” means a product designed, manufactured, produced, marketed, or sold to produce a characterizing flavor when added to a tobacco product.

(16) “Tobacco retailer” means a person who engages in this state in the sale of tobacco products directly to the public from a retail location. “Tobacco retailer” includes a person who operates vending machines from which tobacco products are sold in this state.

(b) (1) A tobacco retailer, or any of the tobacco retailer’s agents or employees, shall not sell, offer for sale, or possess with the intent to sell or offer for sale, a flavored tobacco product or a tobacco product flavor enhancer.

(2) There is a rebuttable presumption that a tobacco product is a flavored tobacco product if a manufacturer or any of the manufacturer’s agents or employees, in the course of their agency or employment, has made a statement or claim directed to consumers or to the public that the tobacco product has or produces a characterizing flavor, including, but not limited to, text, color, images, or all, on the product’s labeling or packaging that are used to explicitly or implicitly communicate that the tobacco product has a characterizing flavor.

(c) Subdivision (b) does not apply to the sale of flavored shisha tobacco products by a hookah tobacco retailer if all of the following conditions are met:

(1) The hookah tobacco retailer has a valid license to sell tobacco products issued pursuant to Chapter 2 (commencing with Section 22971.7) of Division 8.6 of the Business and Professions Code.

(2) The hookah tobacco retailer does not permit any person under 21 years of age to be present or enter the premises at any time.

(3) The hookah tobacco retailer shall operate in accordance with all relevant state and local laws relating to the sale of tobacco products.

(4) If consumption of tobacco products is allowed on the premises of the hookah tobacco retailer, the hookah tobacco retailer shall operate in accordance with all state and local laws relating to the consumption of tobacco products on the premises of a tobacco retailer, including, but not limited to, Section 6404.5 of the Labor Code.

(d) Subdivision (b) does not apply to sales of premium cigars sold in cigar lounges where products are purchased and consumed only on the premises.

(e) Subdivision (b) does not apply to loose leaf tobacco or premium cigars.

(f) A tobacco retailer, or agent or employee of a tobacco retailer, who violates this section is guilty of an infraction and shall be punished by a fine of two hundred fifty dollars (\$250) for each violation of this section.

(g) This section does not preempt or otherwise prohibit the adoption of a local standard that imposes greater restrictions on the access to tobacco products than the restrictions imposed by this section. To the extent that there is an inconsistency between this section and a local standard that imposes greater restrictions on the access to tobacco products, the greater restriction on the access to tobacco products in the local standard shall prevail.

SEC. 2. The provisions of this act are severable. If any provision of this act or its application is held invalid, that invalidity shall not affect other provisions

or applications that can be given effect without the invalid provision or application.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.