UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

OHMHARSH CORP. d/b/a AMPM Convenience Store; AAROHI INC. d/b/a Chrispy's Liquors and Lottery; AJIT CORPORATION d/b/a Bluemoon Smoke & Vape Outlets; NILKANT 136 INC. d/b/a City Smoke Shop; 201 CHEBACCO MARKET, INC. d/b/a Chebacco Market; VISHVESHWARA CORP d/b/a Halifax Cigar & Smoke Shop; RIDHY CORPORATION d/b/a Gj-2 Smoke Shop; TRP CONVENIENCE INC d/b/a EZ Shop; SMITA SMART LLC d/b/a Mansfield Vape and Smoke Shop; MEDFORD SAM'S GAS LLC d/b/a Medford Sams Gas; SARU CORP. d/b/a The Corner Store; RIHAAN CORP. d/b/a Jay's Smoke Shop; D&K SMOKE SHOP LLC d/b/a D&K Smoke; TTEEN CORPORATION d/b/a Station Avenue Convenience; VIVAAN LLC d/b/a One Stop Convenience; and 513 FIVE THIRTEEN INC d/b/a Vaporzone,

Plaintiffs,

v.

ROBBIE GOLDSTEIN, in his official capacity as COMMISSIONER OF THE MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH; TOWN OF BARNSTABLE; CITY OF BEVERLY; CITY OF CAMBRIDGE; TOWN OF DANVERS; TOWN OF ESSEX; TOWN OF HALIFAX; TOWN OF HANOVER; CITY OF LYNN; TOWN OF MANSFIELD; CITY OF MEDFORD; TOWN OF PLYMOUTH; CITY OF SALEM; CITY OF SOMERVILLE; TOWN OF YARMOUTH; TOWN OF MEDWAY; and TOWN OF SAUGUS,

Defendants.

Civil Action No.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Nature of the Action

1. This case challenges a coordinated effort by the Massachusetts Department of Public Health ("MDPH") and the Municipal Defendants, acting through their local boards of health, to enforce the Food and Drug Administration's ("FDA") federal premarket-review requirements through local tobacco-sales permit conditions that neither state nor local law authorizes.

2. Plaintiffs are Massachusetts retailers with valid local tobacco-sales permits. Defendants have ordered Plaintiffs to remove electronic cigarettes, oral nicotine pouches, and other tobacco products from their shelves—not because Plaintiffs violated an independent state or local law, but solely because the FDA has not yet issued Marketing Granted Orders ("MGOs") for those products.

3. Congress assigned tobacco-product premarket review to the FDA. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a manufacturer generally may not introduce a new tobacco product into interstate commerce unless the FDA authorizes its marketing. 21 U.S.C. § 387j. Congress also barred states and their political subdivisions from imposing requirements different from or in addition to federal requirements relating to premarket review. 21 U.S.C. § 387p(a)(2)(A) (**Ex. 1**). And Congress reserved FDCA-enforcement proceedings to the United States. 21 U.S.C. § 337(a) (**Ex. 2**).

4. The FDA decides when and how to enforce federal premarket-review requirements. In May 2026, the FDA announced that it generally does not intend to prioritize enforcement against certain Electronic Nicotine Delivery System ("ENDS") and oral nicotine-pouch products, while retaining enforcement discretion on a case-by-case basis. (**Ex. 8**).

5. MDPH and the Municipal Defendants have nevertheless created a local enforcement regime for federal premarket-review requirements that departs from the FDA's case-specific enforcement approach. In January 2026, MDPH distributed a protocol, template retailer letter, and other materials instructing local officials to require retailers to remove electronic cigarettes and oral nicotine-pouch products without MGOs. (**Ex. 4**). Acting on MDPH's direction, the Municipal Defendants issued substantially similar notices to Plaintiffs and other retailers (the "Enforcement Notices").

6. The Enforcement Notices make the presence or absence of an FDA MGO the measure of compliance with local tobacco-sales permits. They require Plaintiffs to remove products without MGOs and threaten local inspections, violation notices, fines, and adverse permit consequences, including suspension or nonrenewal.

7. That regime is unlawful. It imposes local requirements relating to federal premarket review, uses local permitting authority to enforce a federal regulatory scheme, and threatens sanctions that neither Massachusetts law nor the Municipal Defendants' own tobacco regulations authorize. Defendants may enforce valid, independently adopted tobacco-sales rules. But they may not use local permits to impose coercive local consequences solely for an alleged violation of the FDCA's federal premarket-review requirements. The MGO-based portions of the Enforcement Notices are therefore preempted, ultra vires, and unenforceable.

8. The Enforcement Notices place Plaintiffs' businesses in immediate jeopardy. They threaten substantial inventory losses, reduced revenue and customer traffic, loss of goodwill and companion sales, payroll and lease defaults, adverse permit consequences, and, for several Plaintiffs, closure.

9. Plaintiffs seek a declaration that the MGO-based portions of the Enforcement Notices are preempted, ultra vires, and unenforceable; preliminary and permanent injunctive relief barring Defendants from enforcing those portions; attorneys' fees and costs under 42 U.S.C. § 1988; and such other relief as justice requires.

Jurisdiction and Venue

10. This Court has original subject-matter jurisdiction under 28 U.S.C. § 1331 because Plaintiffs seek prospective declaratory and injunctive relief from state and local action preempted by federal law, including 21 U.S.C. §§ 387p and 337(a), and assert a claim under 42 U.S.C. § 1983.

11. This Court has supplemental jurisdiction under 28 U.S.C. § 1367 over Plaintiffs' Massachusetts-law ultra vires claim because it forms part of the same case or controversy as the federal preemption claims.

12. This Court has authority to issue declaratory relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, and injunctive relief under Fed. R. Civ. P. 65.

13. Venue is proper in this District under 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claims occurred in this District, the Municipal Defendants are situated within this District, and MDPH maintains offices and exercises authority within this District.

14. This Court has personal jurisdiction over Defendants because each Defendant is a Massachusetts official or Massachusetts municipality, and the challenged notices and coordination occurred in Massachusetts.

The Parties

A. Plaintiffs

15. Plaintiff Ohmharsh Corp. d/b/a AMPM Convenience Store is a corporation organized under the laws of the Commonwealth of Massachusetts, with its principal place of

business at 489 Bearses Way, Hyannis, MA 02601. Ohmharsh Corp. holds a Tobacco Product Sales Permit issued by the Town of Barnstable.

16. Plaintiff Aarohi Inc. d/b/a Chrispy's Liquors and Lottery is a corporation organized under the laws of the Commonwealth of Massachusetts, with its principal place of business at 335 Rantoul St., Beverly, MA 01915. Aarohi Inc. holds a Tobacco Product Sales Permit issued by the City of Beverly.

17. Plaintiff Ajit Corporation d/b/a Bluemoon Smoke & Vape Outlets is a corporation organized under the laws of the Commonwealth of Massachusetts, with its principal place of business at 2034 Massachusetts Ave, Cambridge, MA 02139. Ajit Corporation holds a Tobacco Product Sales Permit issued by the City of Cambridge.

18. Plaintiff Nilkant 136 Inc. d/b/a City Smoke Shop is a corporation organized under the laws of the Commonwealth of Massachusetts, with its principal place of business at 136 Andover St., Danvers, MA 01923. Nilkant 136 Inc. holds a Tobacco Product Sales Permit issued by the Town of Danvers.

19. Plaintiff 201 Chebacco Market, Inc. d/b/a Chebacco Market is a corporation organized under the laws of the Commonwealth of Massachusetts, with its principal place of business at 201 Western Ave, Essex, MA 01929. 201 Chebacco Market, Inc. holds a Tobacco Product Sales Permit issued by the Town of Essex.

20. Plaintiff Vishveshwara Corp d/b/a Halifax Cigar & Smoke Shop is a corporation organized under the laws of the Commonwealth of Massachusetts, with its principal place of business at 355 Plymouth St., Halifax, MA. Vishveshwara Corp holds a Tobacco Product Sales Permit issued by the Town of Halifax.

21. Plaintiff Ridhy Corporation d/b/a Gj-2 Smoke Shop is a corporation organized under the laws of the Commonwealth of Massachusetts, with its principal place of business at 228 Columbia Rd, Hanover, MA 02339. Ridhy Corporation holds a Tobacco Product Sales Permit issued by the Town of Hanover.

22. Plaintiff TRP Convenience Inc d/b/a EZ Shop is a corporation organized under the laws of the Commonwealth of Massachusetts, with its principal place of business at 451 Chestnut St., Lynn, MA 01902. TRP Convenience Inc holds a Tobacco Product Sales Permit issued by the City of Lynn.

23. Plaintiff Smita Smart LLC d/b/a Mansfield Vape and Smoke Shop is a limited liability company organized under the laws of the Commonwealth of Massachusetts, with its principal place of business at 266 North Main St., Mansfield, MA 02048. Smita Smart LLC holds a Tobacco Product Sales Permit issued by the Town of Mansfield.

24. Plaintiff Medford Sam's Gas LLC d/b/a Medford Sams Gas is a limited liability company organized under the laws of the Commonwealth of Massachusetts, with its principal place of business at 1 Mystic Ave, Medford, MA 02155. Medford Sam's Gas LLC holds a Tobacco Product Sales Permit issued by the City of Medford.

25. Plaintiff Saru Corp. d/b/a The Corner Store is a corporation organized under the laws of the Commonwealth of Massachusetts, with its principal place of business at 233 Sandwich St., Plymouth, MA 02360. Saru Corp. holds a Tobacco Product Sales Permit issued by the Town of Plymouth.

26. Plaintiff Rihaan Corp. d/b/a Jay's Smoke Shop is a corporation organized under the laws of the Commonwealth of Massachusetts, with its principal place of business at 207 North St.,

Salem, MA 01970. Rihaan Corp. holds a Tobacco Product Sales Permit issued by the City of Salem.

27. Plaintiff D&K Smoke Shop LLC d/b/a D&K Smoke is a limited liability company organized under the laws of the Commonwealth of Massachusetts, with its principal place of business at 147 Highland Ave, Unit D, Somerville, MA 02143. D&K Smoke Shop LLC holds a Tobacco Product Sales Permit issued by the City of Somerville.

28. Plaintiff TTEEN Corporation d/b/a Station Avenue Convenience is a corporation organized under the laws of the Commonwealth of Massachusetts, with its principal place of business at 457 Station Ave, Yarmouth, MA 02664. TTEEN Corporation holds a Tobacco Product Sales Permit issued by the Town of Yarmouth.

29. Plaintiff Vivaan LLC d/b/a One Stop Convenience is a limited liability company organized under the laws of the Commonwealth of Massachusetts, with its principal place of business at 76 Holliston St., Medway, MA. Vivaan LLC holds a Tobacco Product Sales Permit issued by the Town of Medway.

30. Plaintiff 513 Five Thirteen Inc d/b/a Vaporzone is a corporation organized under the laws of the Commonwealth of Massachusetts, with its principal place of business at 184 Broadway, Saugus, MA. 513 Five Thirteen Inc holds a Tobacco Product Sales Permit issued by the Town of Saugus.

B. Defendants

31. Defendant Robbie Goldstein is the Commissioner of the Massachusetts Department of Public Health and is sued in his official capacity. Through MDPH, Commissioner Goldstein promulgates and enforces regulations governing tobacco products and ENDS sales under 105 CMR 665.010 (**Ex. 3**). MDPH directed, coordinated, and facilitated the municipal enforcement

actions challenged here through the Boards of Health Tobacco Control Alliance and its agents, as alleged below.

32. Defendant Town of Barnstable is a municipality organized under the laws of the Commonwealth of Massachusetts.

33. Defendant City of Beverly is a municipality organized under the laws of the Commonwealth of Massachusetts.

34. Defendant City of Cambridge is a municipality organized under the laws of the Commonwealth of Massachusetts.

35. Defendant Town of Danvers is a municipality organized under the laws of the Commonwealth of Massachusetts.

36. Defendant Town of Essex is a municipality organized under the laws of the Commonwealth of Massachusetts.

37. Defendant Town of Halifax is a municipality organized under the laws of the Commonwealth of Massachusetts.

38. Defendant Town of Hanover is a municipality organized under the laws of the Commonwealth of Massachusetts.

39. Defendant City of Lynn is a municipality organized under the laws of the Commonwealth of Massachusetts.

40. Defendant Town of Mansfield is a municipality organized under the laws of the Commonwealth of Massachusetts.

41. Defendant City of Medford is a municipality organized under the laws of the Commonwealth of Massachusetts.

42. Defendant Town of Plymouth is a municipality organized under the laws of the Commonwealth of Massachusetts.

43. Defendant City of Salem is a municipality organized under the laws of the Commonwealth of Massachusetts.

44. Defendant City of Somerville is a municipality organized under the laws of the Commonwealth of Massachusetts

45. Defendant Town of Yarmouth is a municipality organized under the laws of the Commonwealth of Massachusetts.

46. Defendant Town of Medway is a municipality organized under the laws of the Commonwealth of Massachusetts.

47. Defendant Town of Saugus is a municipality organized under the laws of the Commonwealth of Massachusetts.

Factual Allegations

A. Congress made premarket review a federal determination and reserved FDCA enforcement to the United States

48. In 2009, Congress enacted the TCA, Pub. L. No. 111-31, 123 Stat. 1776, and vested the FDA with authority to regulate tobacco products. The TCA establishes a comprehensive federal framework for determining whether a new tobacco product may be marketed, requiring FDA to apply the statutory standard of whether marketing the product is "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2).

49. Under the TCA, federal law—not state or local permitting officials—defines the pathways by which a new tobacco product may obtain federal marketing authorization. See 21

U.S.C. § 387j; 21 C.F.R. § 1114.5. An MGO is an FDA determination issued under that federal framework.

50. Congress also reserved FDCA enforcement authority—including enforcement of the TCA's tobacco provisions—to the federal government. Section 337(a) provides that "all such proceedings for the enforcement, or to restrain violations," of the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a) (**Ex. 2**).

51. The Supreme Court has described § 337(a) as clear evidence that Congress intended the FDCA to be enforced exclusively by the Federal Government. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349, 352 (2001). That allocation allows the FDA to make calibrated enforcement decisions in light of its expertise, resources, and regulatory priorities. Id. at 349–50. The First Circuit likewise holds that § 337(a) preempts claims that exist solely by virtue of an FDCA violation. *DiCroce v. McNeil Nutritionals, LLC*, 82 F.4th 35, 41 (1st Cir. 2023).

52. The TCA's preemption structure contains three related provisions: (a) a Preservation Clause, 21 U.S.C. § 387p(a)(1); (b) a Preemption Clause, 21 U.S.C. § 387p(a)(2)(A); and (c) a Savings Clause, 21 U.S.C. § 387p(a)(2)(B). (**Ex. 1**). The provisions must be read together, giving effect both to Congress's preservation of genuine state and local sales regulation and to its express prohibition on additional requirements relating to federal premarket review.

53. The Preservation Clause confirms that States and municipalities may enact and enforce a "law, rule, regulation, or other measure" concerning tobacco products that is "in addition to, or more stringent than" federal requirements, including measures "relating to or prohibiting the sale" of tobacco products—but only "[e]xcept as provided in paragraph (2)(A)." 21 U.S.C. § 387p(a)(1) (**Ex. 1**).

54. The Preemption Clause then provides that "[n]o 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," a federal requirement relating to, among other subjects, "premarket review." 21 U.S.C. § 387p(a)(2)(A) (**Ex. 1**).

55. The Savings Clause provides that the Preemption Clause does not apply to requirements "relating to the sale" and certain other listed subjects. 21 U.S.C. § 387p(a)(2)(B) (**Ex. 1**). It therefore preserves independently adopted state and local sales standards. It does not authorize a State or municipality to use its permit system to create and enforce a local sanction whose sole rule of decision is whether the FDA has made a federal premarket-review determination.

56. The distinction is consequential. A locality may adopt an independent rule regulating the sale of flavored products, sales to underage purchasers, product placement, or another subject within its lawful authority. But it may not avoid the TCA's express protection of federal premarket review by relabeling as a local "sales" rule a directive that simply makes federal MGO status the dispositive local permit condition.

B. FDA enforcement discretion does not authorize local permit enforcement of federal premarket review

57. The FDA exercises enforcement discretion in administering the federal premarket-review regime. On information and belief, products lacking MGOs remain on the market in circumstances involving pending applications, ongoing review, judicial proceedings, and other product-specific circumstances evaluated by FDA.

58. In May 2026, FDA's Center for Tobacco Products issued guidance titled "Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization" (the "Enforcement Priorities Guidance"). The guidance states that FDA generally

does not intend to prioritize enforcement against specified ENDS and nicotine-pouch products associated with certain pending and accepted applications, while preserving FDA's authority to act case by case. (**Ex. 8**).

59. The Enforcement Priorities Guidance explains that FDA lacks resources to pursue every product lacking authorization and that the guidance does not guarantee that FDA will not act against a particular product. (**Ex. 8**). The guidance does not authorize the sale of any product. It confirms, instead, that federal enforcement decisions are case-specific judgments committed to FDA.

60. The Enforcement Notices displace that federal allocation. They impose automatic local removal directives and local permit consequences based solely on the absence of an MGO, without any independently adopted state or local standard. A local permit regime that substitutes a mandatory municipal sanction for FDA's product-specific enforcement judgment obstructs Congress's decision to reserve FDCA enforcement to the United States. See *Nova Distro, Inc. v. Miyares*, No. 3:25cv857, slip op. at 32–37 (E.D. Va. Dec. 18, 2025) (**Ex. 9**).

C. Massachusetts tobacco law does not make MGO status a local permit condition

61. MDPH has promulgated regulations governing the retail sale of tobacco products and ENDS at 105 CMR 665.000. (**Ex. 3**). Those regulations address defined state-law subjects, including age verification, product placement, nicotine-content limits, flavor restrictions, and documentation requirements.

62. Neither 105 CMR 665.000 nor any other Massachusetts regulation makes FDA MGO status, FDA premarket-review status, or the FDA's product database a condition of a local tobacco-sales permit. The regulations do not authorize a local board of health to impose a local inspection, fine, permit, or renewal consequence solely because FDA has not issued an MGO.

63. Massachusetts also separately prohibits the sale of flavored tobacco products. M.G.L. c. 270, § 28 (**Ex. 10**). That statute regulates a defined product characteristic—"characterizing flavor"—and supplies an independent state-law prohibition. The MGO-based Notices invoke no comparable Massachusetts enactment or independently adopted municipal rule.

D. MDPH coordinated the MGO-based enforcement campaign

64. MDPH directed, coordinated, and facilitated the Enforcement Notices through the Boards of Health Tobacco Control Alliance and its agents. The FDA's December 5, 2025 letter that became the notices' foundation was addressed to Joan E. Hamlett, Director of the Boards of Health Tobacco Control Alliance, a Massachusetts organization.

65. On January 6, 2026, Mary Brush, MDPH's Local Tobacco Program Coordinator, emailed local boards of health and regional tobacco-control directors throughout Massachusetts. (**Ex. 4**). The email, titled "Flavor Enforcement Follow Up Documents," attached guidance for health departments, a retailer letter, the FDA letter, and an MDPH webinar presentation.

66. The attachments included: (a) a guidance document titled "Suggested Protocol for Utilizing FDA Marketing Granted Orders"; (b) a January 2026 template retailer letter; (c) the FDA's December 5, 2025 letter from John Verbeten to Joan Hamlett; and (d) an MDPH webinar presentation. (**Ex. 4**).

67. MDPH instructed local boards of health that retailers "cannot sell any electronic cigarettes or oral nicotine pouches" without an MGO. It directed local officials to require removal, document products remaining on shelves at the next inspection, take photographs, submit information to FDA's illegal tobacco portal, and issue a local notice of violation. (**Ex. 4**).

68. MDPH also provided a template letter stating: "To comply with your local tobacco product sales permit, you must remove all electronic cigarettes and oral nicotine pouches on your

shelves that have not received a Marketing Granted Order from the FDA." (**Ex. 4**). The template did not identify products, identify any local rule that made MGO status a permit condition, or supply an administrative process for deciding what products a retailer must remove.

69. The template warned that, if retailers did not remove the products, the health department would submit information to FDA's illegal tobacco portal and might issue a violation notice. Many Municipal Defendants used materially identical or substantially similar language. (**Ex. 4**).

70. The January 6 email reached the officials who later helped implement the campaign, including Joan Hamlett, Maureen Buzby, the Regional Tobacco Control Director for the Medford region, and other regional directors and local health officials.

71. Medford Board of Health's February 17, 2026 minutes confirm MDPH's direction. (**Ex. 5**). The Board discussed "New FDA Marketing Granted Orders (MGO)" and described the initiative as an "administrative change in tobacco enforcement" that "doesn't require a vote or public hearing" but would affect enforcement.

72. The Medford minutes state that retailers were required to search FDA's website to determine whether each tobacco or nicotine product had an MGO and was not flavored, that many products then sold were not on the list, and that retailers had to remove them. Medford would notify retailers and begin enforcement on May 1, 2026. (**Ex. 5**). The minutes identify no municipal regulation establishing MGO status as a local permit standard.

73. Maureen Buzby attended the Medford meeting as the Regional Tobacco Control Director and was assigned to visit retailers for "education" about the initiative. Violations and fines would be for selling an unauthorized product in Massachusetts. (**Ex. 5**).

74. These materials show more than information sharing. MDPH supplied the operative enforcement protocol, drafted the retailer-facing language, distributed the template letter, and coordinated implementation through regional tobacco-control personnel. The protocol converted a federal status determination into a local permit-compliance command.

75. Local officials acknowledged that they were not creating independent municipal sales rules. The Medford minutes describe an administrative change requiring no vote or public hearing. Everett Board of Health minutes similarly state that no hearing, regulation change, or board approval was necessary because the matter involved federal law. (**Exs. 5–6**).

76. The Enforcement Notices thus make FDA MGO status the sole criterion for local permit compliance and attach local enforcement consequences, even though the Municipal Defendants adopted no MGO-based local regulation, identified no independent local product standard, and supplied no local process for determining what products Plaintiffs allegedly sold in violation of law.

E. The Municipal Defendants issued Enforcement Notices in accordance with MDPH's directives

77. Following MDPH's directives, the Municipal Defendants issued Enforcement Notices that required retailers to remove products without FDA MGOs to comply with local permit requirements and threatened inspections, local violation notices, FDA-portal referrals, fines, and permit-renewal consequences. The notices do not identify a local regulation that makes MGO status a permit condition, a product-specific finding, or a retailer-specific violation of an independently enforceable local standard.

78. Barnstable issued its notice on January 12, 2026, attaching FDA's December 5, 2025 letter. It stated that retailers "must remove all electronic cigarettes and oral nicotine pouches

on your shelves that have not received a Marketing Granted Order from the FDA" to comply with local permit requirements, and warned of FDA-portal reporting and a possible violation notice. (**Ex. 11**).

79. Plymouth issued a similar notice in February 2026, attaching FDA's December 5, 2025 letter and requiring removal of products without MGOs to comply with local permit requirements, with the same FDA-portal and violation warnings. (**Ex. 12**).

80. Hanover issued its notice on March 19, 2026, setting a June 15, 2026 removal deadline. Like the Barnstable and Plymouth notices, it attached the FDA's December 5, 2025 letter, required removal of products without MGOs, and warned of FDA-portal reporting and a possible violation notice. (**Ex. 13**).

81. Cambridge and Somerville, acting through the "6 City Tobacco Initiative," issued a joint notice on March 24, 2026. It required removal of all products without MGOs by May 1, 2026, and warned of onsite inspections beginning that date. (**Ex. 14**).

82. Essex issued its notice on May 6, 2026, following the same template as Barnstable, with strict enforcement beginning July 1, 2026. (**Ex. 15**).

83. Salem issued a similar notice with a July 1, 2026 deadline, warning of FDA-portal reporting and a possible violation notice. (**Ex. 16**).

84. Lynn issued its notice in May 2026, following the same pattern. (**Ex. 17**).

85. Beverly issued its notice on May 1, 2026, attaching the FDA's December 5, 2025 letter. (**Ex. 18**).

86. Halifax issued a notice effective June 1, 2026, following the same pattern and threatening local fines and other enforcement actions. (**Ex. 19**).

87. Mansfield issued its notice on February 18, 2026, with a May 15, 2026 removal deadline and the standard FDA-portal and violation warnings. (**Ex. 20**).

88. Medford issued its notice on March 4, 2026, directing retailer compliance by May 1, 2026, and instructing retailers to prepare for onsite inspection that day, while threatening the same enforcement actions. (**Ex. 21**).

89. Medway issued its notice on May 6, 2026, requiring removal within 30 days with the same enforcement threats. (**Ex. 22**).

90. Saugus issued its notice on May 28, 2026, following the same template as Barnstable. (**Ex. 23**).

91. Yarmouth emailed retailers on April 10, 2026, stating that "[a]s a reminder, information regarding FDA-authorized E-cigarettes and nicotine pouches was distributed to all Yarmouth retailers in January," attaching FDA-authorized product lists and stating that only those products "may be lawfully sold in the United States." The notice also directed immediate removal of the oral nicotine pouch product Zyn Chill as a flavored product prohibited by M.G.L. c. 270, § 28. (**Ex. 24**). On information and belief, Yarmouth's statement that it issued an FDA-based notice to retailers in January refers to the Barnstable Enforcement Notice.

92. On April 30, 2026, Barnstable officials acknowledged that the Town's existing tobacco-permit regulations did not independently authorize local enforcement of the FDCA's federal premarket-review requirements. (**Ex. 7**). After forwarding FDA materials concerning products with marketing authorization, local control officer Bob Collett advised other officials that the Town could enforce its separate flavored-nicotine-product restriction against ZYN Chill, but noted that the Town's regulations did not require retailers to comply with "all local, state and federal laws" as a condition of obtaining or retaining a tobacco permit. He proposed adding that

language to future permit applications. Thomas McKean then directed staff to add a prospective acknowledgment requiring retailers to comply with all federal, state, and local laws. This exchange confirms that Barnstable officials understood the difference between enforcing an independent local flavor rule and using an existing permit to penalize retailers solely for federal MGO status.

93. Danvers issued its notice on May 28, 2026, with a July 1, 2026 removal deadline and the same enforcement threats. (**Ex. 25**).

94. The April 13, 2026 meeting minutes of the Everett Board of Health—one of the Tobacco Initiative municipalities, along with Cambridge and Somerville—confirm a coordinated MDPH campaign to use local tobacco-permit authority to enforce federal premarket-review status without an independently enacted State or municipal rule. (**Ex. 6**).

95. At the meeting, Bonny Carroll and Lisa Stevens, the tobacco-control director for the Massachusetts Municipal Association, explained that the state was "rolling out" enforcement notices to retailers, municipality by municipality, so that local solicitors could review them and municipalities could select their own dates for retailers to remove products without FDA MGOs. (**Ex. 6**).

96. Those officials represented that FDA approval is required before a tobacco product may be sold; characterized products lacking MGOs as "being sold illegally"; and acknowledged that federal law "supersede[s] local and state laws." They further acknowledged that the Commonwealth would not itself enforce these purported federal-law violations because "it is a federal law," but that state tobacco-control officials would report allegedly unlawful products to FDA. Yet the campaign instructed local boards of health to impose consequences themselves: when considering a retailer's tobacco-permit renewal, a board could treat the retailer's sale of products lacking MGOs as a violation of "FDA laws" and decline to issue the permit. The minutes also state

that no new regulation, hearing, or board approval was needed because "the matter concerns federal law." (**Ex. 6**).

97. The minutes thus describe a coordinated effort to cause municipalities to police, punish, and coerce compliance with the FDCA's federal premarket-review regime through local permit decisions, notwithstanding the absence of an independently adopted MGO-based local rule.

F. The Enforcement Notices cause immediate and particularized harm to Plaintiffs

98. Each Plaintiff holds a valid Tobacco Product Sales Permit from its Municipal Defendant and sells electronic cigarettes, oral nicotine pouches, or other products covered by the Enforcement Notices.

99. Plaintiff Smita Smart LLC d/b/a Mansfield Vape and Smoke Shop received Mansfield's Enforcement Notice. Electronic cigarettes, oral nicotine pouches, and vape e-liquid account for about 70% of its sales, roughly $35,000 monthly. The store has about $42,000 in affected inventory. Since receiving the notice, revenue has fallen 60% to 70%. Enforcement would likely force Smita Smart LLC to default on lease, rent, payroll, and other obligations, cut employees' hours, or lay off its employees, and could force the store to close.

100. Plaintiff Vishveshwara Corp d/b/a Halifax Cigar & Smoke Shop received Halifax's Enforcement Notice, effective June 1, 2026. The notice requires every tobacco product to have an MGO, rejects manufacturer letters as insufficient, and warns of fines and other enforcement. E-cigarettes and nicotine pouches generate about 80% of the store's revenue, roughly $40,000 monthly. Enforcement would require removing about $20,000 in inventory, reduce employee hours, and force the store to close.

101. Plaintiff Ajit Corporation d/b/a Bluemoon Smoke & Vape Outlets is subject to the 6 City Tobacco Initiative notice. That notice applied to Cambridge retailers, required removal of

products without MGOs by May 1, 2026, and warned of onsite inspections. Ajit Corporation faces the same removal requirement, inspection risk, and enforcement theory as other 6 City retailers.

102. Plaintiff Nilkant 136 Inc. d/b/a City Smoke Shop received Danvers's Enforcement Notice. About half of the store's business is affected, including roughly $25,000 in monthly revenue and $50,000 in inventory. Customers have already begun traveling to other towns and New Hampshire for the affected products. Nilkant 136 Inc. expects enforcement to eliminate its ability to pay employees and operating expenses, resulting in inspections, penalties, lost customers, layoffs, and closure.

103. Plaintiff D&K Smoke Shop LLC d/b/a D&K Smoke received the 6 City Enforcement Notice. The affected products generate about 60% of its revenue, roughly $20,000 monthly, and represent about $35,000 in inventory. The store has already lost about $10,000 in sales because of the notice. Further enforcement would threaten its lease, business loan, line of credit, equipment financing, supplier obligations, and payroll.

104. Plaintiff Ohmharsh Corp. d/b/a AMPM Convenience Store received Barnstable's January 2026 notice. The notice identifies no allegedly unauthorized product in the store, no inspection, and no specific violation. The affected products generate about $7,000 monthly, and about $3,500 in inventory is at risk. Ohmharsh Corp. has already lost about $4,000 in revenue from the notice and threatened enforcement.

105. Plaintiff Aarohi Inc. d/b/a Chrispy's Liquors and Lottery received Beverly's May 1, 2026 notice. It is addressed generally to tobacco retailers, does not identify the store, and identifies no allegedly unauthorized product on its shelves. Electronic cigarettes and oral nicotine pouches account for about 25% of the store's sales, about $5,000 monthly. Enforcement would

reduce revenue, strand inventory, and divert customers who also buy liquor, lottery tickets, and convenience goods.

106. Plaintiff 201 Chebacco Market, Inc. d/b/a Chebacco Market received Essex's May 6, 2026 notice. The notice identifies no specific product, sale to a minor, customer complaint, or inspection finding. The affected products generate about 30% of the store's revenue, roughly $8,000 monthly, and about $3,500 in inventory is at risk. More than 40% of the store's customers come principally for tobacco and nicotine products and also spend about $1,500 daily on tobacco, beer, liquor, lottery tickets, and convenience goods.

107. Plaintiff Ridhy Corporation d/b/a Gj-2 Smoke Shop received Hanover's March 19, 2026 notice in April 2026. The notice directs removal of non-MGO electronic cigarettes and oral nicotine pouches by June 15, 2026, but does not identify the products at issue or cite a Hanover rule making them unlawful. The affected products generate about 60% of the store's revenue, roughly $15,000 monthly, and represent about $25,000 in inventory. Enforcement would threaten two employees' jobs and likely force the store to close.

108. Plaintiff TRP Convenience Inc d/b/a EZ Shop received Lynn's May 2026 notice. The notice is addressed generally to "Tobacco Retailers," identifies no specific product at EZ Shop, and directs retailers to check every product against FDA's online database. The affected products generate about 35% of EZ Shop's revenue, about $15,000 monthly. Enforcement would strand about $3,000 in inventory and reduce sales of other goods bought by the same customers.

109. Plaintiff Medford Sam's Gas LLC d/b/a Medford Sams Gas received Medford's March 4, 2026 notice on March 10, 2026. The notice directs removal by May 1, 2026, requires the store to prepare for an onsite inspection that day, and warns of FDA-portal reporting and a violation notice. The targeted products produce about $28,000 monthly, roughly 25% of store revenue. Since

receiving the notice, Medford Sam's Gas has lost about $7,500 in sales and faces about $25,500 in monthly tobacco and related sales at risk, plus about $4,500 in inventory that would have to be removed.

110. Plaintiff Saru Corp. d/b/a The Corner Store received Plymouth's February 2026 notice. Enforcement would force the store to remove affected inventory, lose its purchase cost, and face FDA-portal reporting and a violation notice that could jeopardize its tobacco-sales permit. The Corner Store has already lost sales of affected products, and further enforcement threatens its ability to remain open.

111. Plaintiff Rihaan Corp. d/b/a Jay's Smoke Shop received Salem's notice on May 5, 2026. The notice sets a July 1, 2026 deadline and threatens FDA-portal reporting and a violation notice. The affected products generate about 59% of the store's revenue, roughly $30,000 monthly, and the store has about $20,000 in affected inventory. Without that revenue, Rihaan Corp. expects prompt defaults and ultimately closure, with the loss of customer relationships and goodwill built over years.

112. Plaintiff TTEEN Corporation d/b/a Station Avenue Convenience received Yarmouth's April 10, 2026 email attaching FDA-authorized-product guidance. Since receiving the notice, TTEEN Corporation has lost about $3,000 in sales. Enforcement would require removing about $3,500 in inventory. The affected products generate about $5,000 monthly, and their removal would reduce customer traffic and related sales of food, drinks, lottery tickets, and other goods.

113. Plaintiff Vivaan LLC d/b/a One Stop Convenience received Medway's May 6, 2026 notice on May 8, 2026. The notice is addressed to the store, requires removal within 30 days, and threatens FDA-portal reporting and a violation notice. Electronic cigarettes and oral nicotine pouches account for about 10% of the store's revenue, about $7,000 monthly. Enforcement would

strand about $4,000 in inventory, reduce companion grocery and lottery sales, put rent, loans, supplier accounts, and payroll at risk, and threaten the jobs of two employees.

114. Plaintiff 513 Five Thirteen Inc d/b/a Vaporzone received Saugus's May 28, 2026 notice. The notice identifies no specific product that must be removed but orders the store to clear electronic cigarettes and nicotine pouches from its shelves. Those products generate about 80% of Vaporzone's revenue, roughly $16,000 monthly. Vaporzone has about $36,000 in affected inventory, has already seen reduced customer traffic, and faces layoffs, permit consequences, and closure if Saugus enforces the notice.

G. No Municipal Defendant adopted an MGO-based local rule or supplied a lawful local standard for permit enforcement

115. Neither the Municipal Defendants' existing tobacco regulations nor Massachusetts regulations at 105 CMR 665.000 makes FDA premarket-review status a condition of a local tobacco-sales permit. The Enforcement Notices cite no independent local regulation that does so. They do not identify a particular product Plaintiffs sold, a retailer-specific inspection finding, or an existing local rule allegedly violated. Instead, they direct retailers to investigate FDA materials and remove whatever products the retailers themselves determine may lack MGOs.

116. The Medford and Everett minutes confirm that the Municipal Defendants did not adopt an independent local sales rule. Officials stated that no hearing, regulation change, or board approval was necessary because the initiative involved federal law and was merely an "administrative change." (Exs. 5–6). Yet the notices impose coercive local consequences. A municipality cannot create a new permit condition through an informal directive while disavowing the rulemaking that would be required to adopt a local regulation.

117. The harm is immediate and irreparable. The Enforcement Notices threaten not only sales of affected products but also customer traffic, companion sales, inventory value, payroll, goodwill, permits, and continued operations. A damages award after judgment could not restore lost customers, undo permit consequences imposed through an unlawful local enforcement regime, or reopen a closed store.

CAUSES OF ACTION

COUNT I – Express Preemption Under 21 U.S.C. § 387p(a)(2)(A) (Against All Defendants)

118. Plaintiffs reallege and incorporate the preceding allegations.

119. The TCA's Preemption Clause provides that no State or political subdivision may establish or continue a tobacco-product requirement that differs from or adds to federal requirements relating to, among other subjects, "premarket review." 21 U.S.C. § 387p(a)(2)(A) (**Ex. 1**).

120. The Enforcement Notices impose local requirements relating to premarket review. They make compliance with a local tobacco-sales permit turn solely on whether FDA has issued an MGO under 21 U.S.C. § 387j. The notices do not apply an independently adopted local product characteristic, sales standard, or permit condition. They direct retailers to determine MGO status and impose local consequences if a retailer does not remove products based on that federal determination.

121. The Notices add to the federal premarket-review scheme by attaching independent local consequences to MGO status, including local inspections, violation notices, fines, FDA-portal referrals, and permit-renewal consequences. They also differ from the federal scheme by imposing an automatic local removal mandate without the product-specific enforcement judgments Congress assigned to FDA.

122. The Savings Clause does not preserve the Enforcement Notices. The Clause preserves independently adopted State and local requirements "relating to the sale" of tobacco products. 21 U.S.C. § 387p(a)(2)(B). But Defendants did not adopt a local sales standard. The notices' sole operative trigger is federal MGO status. They therefore regulate—and locally enforce—federal premarket review, not an independent State or municipal sale restriction.

123. This case differs from *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71 (1st Cir. 2013). Providence enacted a local ordinance that independently regulated a product characteristic: flavor. *Id.* at 83–84. The First Circuit held that the ordinance was a preserved sales regulation. *Id.* Here, Defendants adopted no ordinance or regulation, identified no local product characteristic, and made no independent local determination. They used local permits to impose consequences solely because FDA has or has not issued an MGO.

124. The fact that the Notices operate through a retailer's ability to sell products does not transform this federal premarket-review enforcement mechanism into an independently adopted local sales rule. Congress did not preserve local authority to impose a local permit sanction whenever a municipal official believes federal premarket-review law has been violated. The opposite rule would erase the TCA's express preemption of State and local requirements relating to premarket review.

125. Persuasive authority confirms the distinction. In *Nova Distro*, the court held that provisions conditioning lawful sale or imposing penalties entirely on FDA premarket-authorization determinations were preempted because they were contingent on FDA determinations and conflicted with the federal enforcement framework. (**Ex. 9**). Here, the Enforcement Notices also use FDA MGO status as the sole rule of decision and add local enforcement consequences in addition to and different from the FDA's enforcement priorities and case-by-case discretion.

126. The Enforcement Notices are preempted under 21 U.S.C. § 387p(a)(2)(A), to the extent they make local permit compliance, inspection, penalty, or permit-renewal consequences turn solely on FDA MGO status or alleged noncompliance with federal premarket-review requirements, and are unenforceable.

COUNT II – Equitable Action to Enjoin State and Local Enforcement Preempted by 21 U.S.C. § 337(a) and the Supremacy Clause

127. Plaintiffs reallege and incorporate the preceding allegations.

128. This is an action for prospective declaratory and injunctive relief from state and local action preempted by federal law. Section 337(a) provides that FDCA-enforcement proceedings "shall be by and in the name of the United States." 21 U.S.C. § 337(a) (**Ex. 2**). Plaintiffs do not seek to enforce the FDCA or to compel FDA action. They seek to prevent Defendants from using local permit power to impose coercive local consequences solely for an alleged violation of the federal premarket-review requirement.

129. The Enforcement Notices constitute state and local enforcement of federal premarket-review requirements. They direct retailers to remove products solely because of FDA MGO status, impose local consequences for noncompliance with that federal status, and treat MGO status as a local permit condition. Defendants do not identify an independently adopted local product rule or sales standard that supplies a separate basis for these directives.

130. That local regime obstructs Congress's decision to reserve FDCA enforcement to the United States. *Buckman* recognizes that § 337(a) reflects Congress's decision to leave FDCA enforcement to the federal government. 531 U.S. at 349–50. A municipality cannot do indirectly through permit coercion what Congress reserved to the United States by characterizing an alleged federal violation as a local permit violation without a separate local rule.

131. The Notices also displace FDA's enforcement discretion. FDA's May 2026 guidance confirms that federal enforcement of premarket-review requirements involves case-specific priorities and judgments. (**Ex. 8**). Defendants' blanket removal commands substitute an automatic local sanction for those federal judgments.

132. The Enforcement Notices are impliedly preempted and unenforceable to the extent they impose local enforcement consequences based solely on FDA MGO status or alleged noncompliance with federal premarket-review requirements.

COUNT III – 42 U.S.C. § 1983 (In the Alternative); Deprivation of Rights Secured by 21 U.S.C. § 387p(a)(2)(A)
(Against All Municipal Defendants)

133. Plaintiffs reallege and incorporate the preceding allegations.

134. Each Municipal Defendant, acting through its board of health, health department, or final policymaking officials, issued, adopted, ratified, implemented, or enforced an Enforcement Notice directing Plaintiffs to remove electronic cigarettes and oral nicotine pouches based on FDA MGO status. The Notices made local permit compliance turn on federal premarket-review status and threatened inspections, local violation notices, FDA-portal referrals, fines, and permit-renewal consequences.

135. Each Municipal Defendant acted under color of State law and pursuant to municipal policy, custom, or a decision by officials with final policymaking authority over local tobacco-permit enforcement. By issuing and enforcing the Notices, the Municipal Defendants deprived Plaintiffs of rights secured by 21 U.S.C. § 387p(a)(2)(A).

136. Section 387p(a)(2)(A) uses mandatory language directed at States and political subdivisions: "No State or political subdivision of a State may establish or continue in effect" a prohibited requirement. 21 U.S.C. § 387p(a)(2)(A). The statutory command protects regulated

parties, including Plaintiffs, from local requirements that Congress expressly prohibited. Plaintiffs are the direct objects of the local requirements imposed here.

137. Section 1983 supplies a remedy for the deprivation of rights secured by federal statute where the statute unambiguously protects Plaintiffs and Congress has not foreclosed that remedy. Section 387p(a)(2)(A)'s text, structure, and purpose demonstrate Congress's intent to protect regulated parties from the precise State and local requirements Plaintiffs challenge.

138. The Municipal Defendants are "persons" subject to prospective relief under § 1983. The challenged Notices are official municipal policy or were issued or ratified by officials with final policymaking authority over tobacco-permit enforcement.

139. The Municipal Defendants' actions have caused, and continue to cause, irreparable harm, including lost revenue, stranded inventory, threatened permit consequences, loss of goodwill and customer traffic, and the chilling of Plaintiffs' ability to conduct their businesses free from preempted local enforcement.

COUNT IV – Ultra Vires Enforcement Without State or Local Regulatory Authority (Against All Municipal Defendants)

140. Plaintiffs reallege and incorporate the preceding allegations.

141. The Municipal Defendants lack authority to enforce FDA premarket-review status as a condition of local tobacco-sales permits. Massachusetts law authorizes boards of health to make reasonable health regulations. M.G.L. c. 111, § 31. But no Municipal Defendant adopted or published a regulation incorporating FDA MGO status, federal premarket-review status, or the FDA's product database as a condition of sale, inspection, fine, suspension, or permit renewal.

142. Massachusetts tobacco law and 105 CMR 665.000 regulate defined subjects and authorize enforcement of valid State and local tobacco rules. M.G.L. c. 270, § 28 separately prohibits flavored tobacco products. But neither the statutes nor the regulations authorize a

municipality to impose local permit consequences solely for alleged noncompliance with the FDCA's premarket-review provisions.

143. The Municipal Defendants did not adopt an MGO-based tobacco regulation, publish a regulation establishing MGO status as a local permit condition, or make retailer-specific findings under an existing local standard. They instead proceeded on the stated premise that no local rulemaking was required because the initiative involved "federal law." A generic permit condition requiring compliance with applicable law does not itself create a local enforcement power to police every FDCA provision, particularly where Congress reserved FDCA enforcement to the United States.

144. The Enforcement Notices are ultra vires and exceed the Municipal Defendants' delegated authority to the extent they impose or threaten local inspections, violations, fines, permit consequences, or other coercive measures solely because FDA has not issued an MGO or because a retailer allegedly violates the federal premarket-review requirement.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and grant the following relief:

I. A declaratory judgment under 28 U.S.C. §§ 2201–2202 declaring that the MGO-based portions of the Enforcement Notices are preempted by 21 U.S.C. § 387p(a)(2)(A) and 21 U.S.C. § 337(a), exceed the Municipal Defendants' authority, and are unenforceable to the extent they make local permit compliance or local enforcement consequences turn solely on FDA MGO status or alleged noncompliance with federal premarket-review requirements;

II. A preliminary injunction under Fed. R. Civ. P. 65 enjoining the Commissioner, MDPH's officers, agents, employees, and persons acting in concert with them, and the Municipal Defendants and their officers, agents, employees, and persons acting in concert with them, from enforcing, implementing, or taking coercive action to carry out the MGO-based portions of the Enforcement Notices while this action is pending, where the asserted basis for the action is solely FDA MGO status or alleged noncompliance with federal premarket-review requirements and not an independently enforceable State or local tobacco rule;

III. A permanent injunction enjoining the Commissioner, MDPH's officers, agents, employees, and persons acting in concert with them, and the Municipal Defendants and their officers, agents, employees, and persons acting in concert with them, from enforcing, implementing, or taking coercive action to carry out the MGO-based portions of the Enforcement Notices, including by issuing local violation notices, conducting an inspection solely to enforce MGO status, imposing fines or permit-renewal consequences, or otherwise using local tobacco-permit authority based solely on FDA MGO status or alleged noncompliance with federal premarket-review requirements;

IV. If Plaintiffs prevail under 42 U.S.C. § 1983, reasonable attorneys' fees and costs under 42 U.S.C. § 1988; and

V. Any other relief the Court deems just and proper.

Respectfully submitted,

PLAINTIFFS,

By their attorneys,

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