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Guidance Document

Suggested Protocol for Utilizing FDA Marketing Granted Orders

Most Massachusetts local tobacco sales regulations require applicants for a Tobacco Product Sales Permit to sign a statement affirming their responsibility to inform all employees selling tobacco of all applicable federal, state and local laws, rules and regulations. This includes the current FDA requirement that only products with Marketing Granted Orders¹ may be sold in the United States, as described in the attached December 5, 2025 letter from John Verbeten, Director of the Office of Compliance and Enforcement Center for Tobacco Products at the FDA. Currently, only a limited number of electronic cigarettes and an even smaller number of oral nicotine pouches have been granted these authorizations.

It is best practice to include in the permit application: “The applicant acknowledges tobacco retailers must comply with all federal, state, and local laws, rules, regulations, and requirements.” However, even if this is not included in the application, all permit holders and their employees are required to comply with local, state and federal laws, rules, regulations, and requirements, including the FDA Marketing Granted Orders.

It is recommended to notify retailers about this policy and its implications for enforcement. A sample template letter is attached hereto. Retailers cannot sell any electronic cigarettes or oral nicotine pouches that lack a Marketing Granted Order. **To verify which products are authorized by the FDA, retailers can consult the FDA’s “Searchable Tobacco Products Database,” accessible at the FDA website: www.fda.gov/tobacco-products.**

It is further recommended to remind retailers and permit applicants that Massachusetts imposes additional requirements beyond what is required by the FDA. For instance, even tobacco products with a characterizing flavor that have obtained a Marketing Granted Order cannot be sold in Massachusetts. The sale of tobacco products, including electronic cigarettes and oral nicotine pouches, with a characterizing flavor other than tobacco is prohibited under Massachusetts law.

Products found on retail store shelves without a Marketing Granted Order should be removed by the retailer. If these products are still present during the next inspection, document this on the

¹ A “Marketing Granted Order” means that the product has been authorized by the FDA and can be lawfully marketed in the United States.

inspection sheet in the field notes section, capture photographic evidence, and inform the retailer that the relevant details will be submitted to the FDA illegal tobacco portal, and issue a notice of violation of the local regulations. At the request of the retailer, the Board of Health may subsequently hold a hearing.

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