OFFICE OF THE ARIZONA ATTORNEY GENERAL

KRIS MAYES
ATTORNEY GENERAL

CIVIL LITIGATION DIVISION
CONSUMER PROTECTION & ADVOCACY SECTION
TOBACCO ENFORCEMENT UNIT

HOWARD COHEN
ASSISTANT ATTORNEY GENERAL
DIRECT PHONE NO. (602) 542-8069
HOWARD.COHEN@AZAG.GOV

April 22, 2024

7 Eleven
Ms. Donna Bucella
3200 Hackberry Road
Irving, TX 75063
Donna.Bucella@7-11.com

Re: Sale of Unauthorized Tobacco Products

Dear Ms. Bucella:

On behalf of the Arizona Attorney General's Office ("AGO"), I am writing to 7 Eleven as a current partner in preventing the sales of tobacco products to minors to request that it continues to work with us to ensure that systems are in place to prevent the sale of certain prohibited electronic nicotine devices ("ENDS") and oral nicotine products (including nicotine pouches). These include products containing nicotine and synthetic nicotine (nicotine not made or derived from tobacco).

To be legally sold, ENDS and oral nicotine products must obtain a marketing granted order ("MGO") from the Food and Drug Administration ("FDA"). To date, the FDA has issued MGOs for 23 tobacco flavored ENDS products (no other flavors have been authorized), and 4 oral nicotine products. All other ENDS or oral nicotine products that are not on this list have not been authorized by FDA, making such products illegal and adulterated and misbranded under Sections 902 and 903 of the Federal Food, Drug, and Cosmetic Act. In other words, those products cannot be sold in Arizona. The FDA has created a list of tobacco products that have been granted a MGO allowing the product to be sold in the USA. This list is updated as new MGOs are granted. That list is available at the following link:

https://www.accessdata.fda.gov/scripts/searchtobacco/

Background Information on the FDA's Premarket Review

Every new tobacco product is subject to the FDA's premarket review pursuant to 21 U.S.C. § 387j(a)(2), and must receive an order from the FDA under 21 U.S.C. § 387j(c)(1)(A)(i) authorizing the sale of the product in the USA. The Tobacco Control Act requires premarket authorization of a new tobacco product to be denied unless the FDA finds that marketing the product is "appropriate for the protection of the public health."[1] Under federal law, unauthorized tobacco products are considered adulterated pursuant to 21 U.S.C. § 387b(6)(A). It is forbidden to market, sell, purchase, or distribute adulterated tobacco products. Under the law, no tobacco product (including ENDS and oral nicotine products) may legally enter the market for sale without having first received authorization by the FDA that the product is "appropriate for the protection of public health." Companies distributing or selling any such unauthorized products are subject to enforcement penalties by the FDA, which may include a civil monetary penalty or no-tobacco-sale order. Retailers and distributors engaged in the sale or distribution of such unauthorized products risk liability. To date, the FDA has only authorized the marketing of 23 tobacco-flavored ENDS and 4 oral nicotine products.

The AGO recognizes that many Arizona retailers are interested in full voluntary compliance with all laws and that you have served as a partner in preventing youth access to tobacco products through your Assurances of Voluntary Compliance. Therefore, please see that you take steps to ensure that you do not offer for sale, sell, ship, or knowingly assist in the sale or shipment of adulterated/unauthorized products into Arizona, and only sell ENDS and oral nicotine products on the FDA list.

Please feel free to share this letter with any manufacturers, wholesalers, retailers, or any other interested parties. If you have any questions, please feel free to contact me via email at Howard.Cohen@azag.gov.

Sincerely,

Howard Cohen
Assistant Attorney General
Tobacco Enforcement Unit

[1] 21 U.S.C. § 387j(c)(2), (4)

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April 22, 2024

7 Eleven
Ms. Erin Doherty
3200 Hackberry Road
Irving, TX 75063
erin.doherty@7-11.com

Re: Sale of Unauthorized Tobacco Products

Dear Ms. Doherty:

On behalf of the Arizona Attorney General's Office ("AGO"), I am writing to 7 Eleven as a current partner in preventing the sales of tobacco products to minors to request that it continues to work with us to ensure that systems are in place to prevent the sale of certain prohibited electronic nicotine devices ("ENDS") and oral nicotine products (including nicotine pouches). These include products containing nicotine and synthetic nicotine (nicotine not made or derived from tobacco).

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Please feel free to share this letter with any manufacturers, wholesalers, retailers, or any other interested parties. If you have any questions, please feel free to contact me via email at Howard.Cohen@azag.gov.

Sincerely,

Howard Cohen
Assistant Attorney General
Tobacco Enforcement Unit

[2] 21 U.S.C. § 387j(c)(2), (4)