July 26, 2022

Dr. Brian King
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: Lack of FDA enforcement against products subject to marketing denial orders

Dear Dr. King:

The undersigned public health and medical organizations write to express our deep concern regarding the Food and Drug Administration's (FDA) failure to take enforcement actions against new tobacco products, including youth-appealing flavored e-cigarettes, that have received marketing denial orders (MDOs) yet remain on the market illegally. FDA's lack of action against these products, which the agency claims are among its highest enforcement priorities, imperils the health of our nation's youth.

Although all new tobacco products that are on the market without the statutorily required premarket authorization are marketed unlawfully, FDA has identified certain types of products as enforcement priorities. Specifically, FDA has stated that "unauthorized electronic nicotine delivery system (ENDS) products for which no application is pending, including, for example, *those with an MDO*, are among our highest enforcement priorities."[1] Despite the agency's stated priorities, many of the products subject to MDOs remain available on the market illegally, apparently free from FDA enforcement.

Take, for example, the cases of Breeze Smoke, LLC and 7 Daze LLC. After receiving MDOs, these two companies sued FDA in federal court. Each company filed a motion to stay its MDO during the courts' consideration of the merits of the orders – effectively asking the courts to require FDA to allow the companies to continue to sell their products during the pendency of

[1] *E.g.*, FDA News Release, *FDA Denies Authorization to Market Juul Products* (June 23, 2022), https://www.fda.gov/news-events/press-announcements/fda-denies-authorization-market-juul-products (emphasis added).

the litigation.[2] FDA opposed the motions;[3] and the courts, siding with FDA, denied the motions.[4] Therefore, the MDOs issued to these companies are in full effect and any product subject to the MDOs that remains on the market is illegal and among the agency's self-proclaimed "highest enforcement priorities."

Nonetheless, the Breeze Smoke and 7 Daze products that were denied authorization remain on the market, readily available for purchase. And FDA appears to have taken no enforcement action against either company's products.

Through court filings, lists of the Breeze Smoke and 7 Daze products that were denied authorization are publicly available.[5] A quick internet search reveals that these denied products remain on the market. For example, multiple retailers continue to illegally sell 7 Daze's denied products, including products such as "Reds Apple Grape ICED," "Reds Apple Mango," and "Reds Apple Strawberry."[6] Breeze Smoke's denied products are similarly still being marketed illegally. The MDO issued to Breeze Smoke covers certain of its Breeze Plus line of products.[7] These denied Breeze Plus products, including Blueberry Lemon and Watermelon Mint, remain readily available for purchase from multiple retailers.[8] Moreover, brick-and-mortar stores continue to sell Breeze Smoke's denied products.[9] Not only are these products being sold illegally but, as can be seen in Attachment 2, they are also falsely advertised as an "FDA/PMTA

[2] Motion for a Stay Pending Review and to Expedite Review, *Breeze Smoke, LLC v. FDA*, 18 F.4th 499 (6th Cir. 2021) (No. 21-3902), ECF 8-1 ("Breeze Smoke Motion"); Emergency Motion under Circuit Rule 27-3 for Stay Pending Appeal and an Administrative Stay Pending the Disposition of this Motion, *7 Daze LLC v. FDA*, No. 21-71319 (9th Cir. Apr. 5, 2022), ECF 20-1 ("7 Daze Motion").

[3] Opposition to Emergency Motions for Stay Pending Review and Administrative Stay, *Breeze Smoke*, 18 F.4th 499 (6th Cir. 2021), ECF 16-1; Opposition to Petitioner's Motion for a Stay Pending Review, *7 Daze*, No. 21-71319 (9th Cir. Apr. 13, 2022), ECF 23-1.

[4] *Breeze Smoke*, 18 F.4th 499 (6th Cir. 2021); Order, *7 Daze*, No. 21-71319 (9th Cir. Apr. 20, 2022), ECF 30.

[5] *See* Breeze Smoke Motion at A5; 7 Daze Motion at App. 11. Because FDA generally has been identifying only the companies that received MDOs, rather than the specific products subject to the MDOs, it is extremely difficult – and often impossible – to assess whether a specific product that is being marketed has been denied authorization, except in cases where the company has filed a legal challenge against the MDO and disclosed the product list.

[6] *E.g.*, *7 Daze MFG Vape Juice*, WEST COAST VAPE SUPPLY, https://westcoastvapesupply.com/collections/7-daze-e-liquid, (last visited July 14, 2022); *7 Daze E-Liquid*, VAPE SOCIETY SUPPLIES, https://vapesocietysupplies.com/collections/all-e-juice-brands/7-daze-e-liquid/ (last visited July 14, 2022).

[7] Breeze Smoke Motion at A356 (affidavit from Breeze Smoke Managing Member noting that the company submitted separate PMTAs for its "Breeze Pro" line of products).

[8] *E.g.*, *Breeze Smoke Plus*, THE HOOKAH SHOP, https://thehookahshop.com/product/breeze-smoke/ (last visited July 14, 2022); *Breeze Plus Disposable Vape*, THE VAPOR SHOPPE, https://thevaporshoppeusa.com/products/breeze-disposable-vape (last visited July 14, 2022).

[9] *See, e.g.*, Attachment 1 (photograph taken on July 15, 2022 at Mid-Pointe Convenience Store, 4199 Werth Road, Alpena, MI 49707 of the denied Breeze Plus Strawberry Cream products being offered for sale).

Accepted Device" with reference to the company's PMTA number[10] (which matches the number of the PMTA that was denied).[11]

It is also worth noting that some retailers selling the denied Breeze Plus products now market them as containing "tobacco-free nicotine."[12] Regardless of their nicotine source, these products are on the market illegally and subject to FDA enforcement. In March 2022, Congress extended FDA's tobacco product authority to cover products "containing nicotine from any source."[13] As part of that law, Congress allowed for a transition period in which certain non-tobacco nicotine products (so-called "synthetic nicotine products") would not be subject to FDA enforcement until July 13, 2022, provided they sought marketing authorization within a specified time period. However, if FDA previously denied a marketing application for a tobacco-derived version of the product, the new synthetic nicotine version was not eligible for this same transition period. Instead, these products were subject to FDA enforcement beginning on May 14, 2022 (60 days after the law's enactment).[14] Therefore, any of the denied Breeze Smoke products that now claim to contain tobacco-free nicotine have been illegal to market for months.

Despite being among the agency's highest enforcement priorities, FDA appears to have taken no enforcement action against any of the 7 Daze or Breeze Smoke products that were denied authorization. When companies are found to be illegally marketing tobacco products, FDA typically first issues a warning letter seeking to achieve voluntary compliance before proceeding to other enforcement actions.[15] A search of FDA's warning letters database[16] reveals that the agency has sent no warning letters regarding any 7 Daze or Breeze Smoke products since their MDOs were issued. FDA's failure to take even this first step in the enforcement process is unacceptable.

These products are merely two examples of products that should no longer be on the market. FDA's inaction with regard to enforcement is emboldening manufacturers to leave on the market products that have been denied marketing orders, and to flood the market with additional products that have not met the standard set by law. Leaving illegal products on the market with no action from FDA does not protect public health. We strongly urge the agency to follow through on its stated priorities and enforce the law against products that have been denied authorization, as well as products that have not bothered to submit applications for FDA review

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[10] Attachment 2 (photograph taken on July 20, 2022 at Mid-Pointe Convenience Store, 4199 Werth Road, Alpena, MI 49707).

[11] *Compare* Attachment 2, *with* Breeze Smoke Motion at A1.

[12] *Breeze Plus Disposable Pod Device 800 Puffs 5.0% Salt Nic 3.5ml 10ct Display*, DANK SHOP, https://dankshop.com/product/breeze-plus-disposable-pod-device-800-puffs-5-0-salt-nic-3-5ml-10ct-display (last visited July 14, 2022).

[13] H.R. 2471, 117th Cong. § 111(a)(1).

[14] *Id.* § 111(d).

[15] FDA, *FDA Continues to Implement Law, Regulate Non-Tobacco Nicotine Products, Warns Retailers and Manufacturers Against Illegal Sales* (July 13, 2022), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-continues-implement-law-regulate-non-tobacco-nicotine-products-warns-retailers-and-manufacturers.

[16] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters.

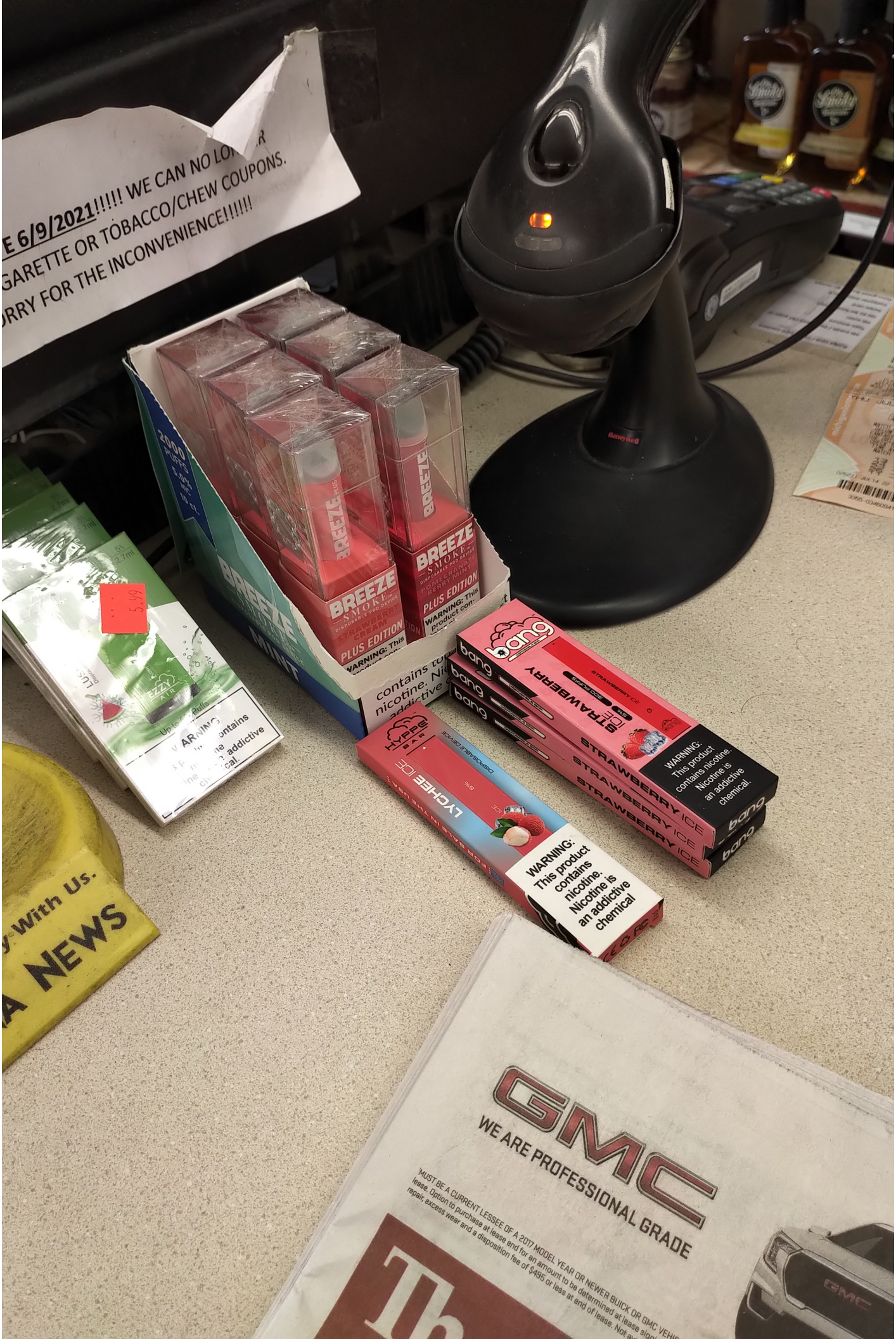
in the first place, including the flavored products contributing to the ongoing youth e-cigarette epidemic.

Sincerely,

American Academy of Pediatrics
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Campaign for Tobacco-Free Kids
Parents Against Vaping e-cigarettes (PAVe)
Truth Initiative

Cc: The Honorable Dr. Robert M. Califf, FDA Commissioner

Attachment 1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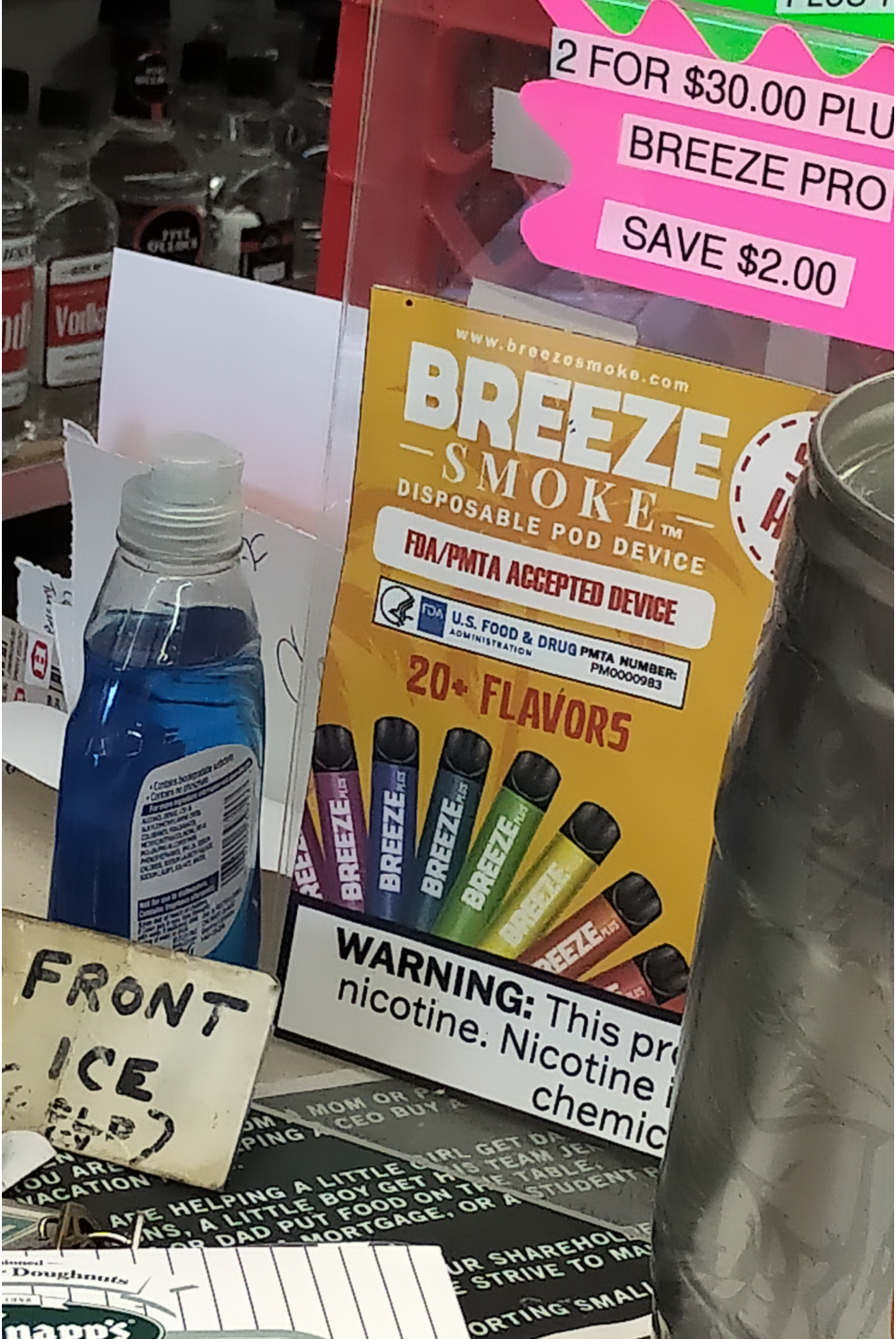
Attachment 2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