



May 8, 2019

Via FedEx

Norman E. Sharpless, M.D.
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

**RE: Walmart Inc.'s Written Response to
Then-Commissioner Scott Gottlieb, M.D.'s April 5 Letter**

Dear Acting Commissioner Sharpless:

Thank you for the letter dated April 5. We appreciate the work the U.S. Food and Drug Administration (FDA) is doing to keep tobacco products out of the hands of minors. We share that goal and agree that preventing the sale of tobacco products to minors is critical. We take seriously our related responsibilities as a retailer and are committed, as described in part below, to taking further steps aimed at preventing these sales in our stores and clubs.

Before turning to those steps, we would like to clarify our historical compliance rates and highlight some of our existing controls and efforts relating to underage tobacco sales. Since 2010, the FDA has conducted approximately 12,800 retailer compliance checks involving minors at Walmart stores and Sam's Club locations. Over that period, Walmart and Sam's Club passed 93% and 99%, respectively, of those checks. Most recently, in 2018, Walmart stores passed 94% of the more than 2,400 FDA checks, and Sam's Club passed 100% of its 15 FDA checks. While we are not satisfied with falling short of our companywide goal of 100% compliance, those compliance rates nonetheless are significantly higher than the rates referenced in Dr. Gottlieb's April 5 letter—and, in our view, more fairly and accurately portray our performance.

We achieved those rates through the implementation and execution of a robust compliance program, which includes the following controls and elements:

- We maintain a comprehensive Sale of Tobacco Products and Paraphernalia Policy and a compliance team fully dedicated to compliance with applicable laws and regulations relating to the sale of alcohol, tobacco, and firearms;



- We require all tobacco sales to be associate (employee) assisted and all tobacco products to be kept in a locked case or in an area behind a register that is blocked from customer access;
- We post store signage identifying the age at which we require customers to show identification to purchase tobacco products. While the law requires us to ID only those customers who appear to be under the age of 27, our Walmart stores have a more-restrictive policy and require—including through the use of automated register prompts and controls—ID from customers who appear to be under the age of 40;
- We require associates who sell or supervise the sale of tobacco products to complete training and testing, and periodic retraining and retesting, on age-verification requirements and methods, the negative health effects of tobacco use, and the importance of preventing the sale of tobacco products to minors; and
- We routinely monitor the execution of age-verification controls and processes by utilizing a third party to execute our secret-shopper program. In 2019, we plan to conduct approximately 8,000 secret-shopper visits. Associates and stores that fail secret-shopper checks—and, for that matter, regulatory checks—are required to complete a corrective action plan.

While continuing to focus on more consistently executing the above controls and processes, we are also implementing additional measures to enhance our compliance rates. For example, we are strengthening the disciplinary action stemming from failed secret-shopper checks. Historically, we imposed associate discipline for failed regulatory checks but not for failed secret-shopper checks. We used failed secret-shopper checks as opportunities to reeducate cashiers, reinforce training, and provide individual instruction on the importance of age verification. Going forward, however, a cashier who fails a secret-shopper check will be subject to disciplinary action, up to and including termination. This new disciplinary protocol, which went into effect last month, mirrors our pre-existing protocol for failed regulatory checks, including FDA checks. Relatedly, we are designing, and plan to implement, a stronger positive-reinforcement protocol to recognize associates and stores that successfully and consistently pass secret-shopper and regulatory checks.

Additionally, we plan to upgrade and reinforce our age-verification training through the use of virtual-reality technology. Virtual reality will allow associates to experience a variety of scenarios and master appropriate responses to reduce the likelihood of sales of age-restricted products to minors.

Further, we are enhancing our use of data, analytics, and systems. Through enhanced analyses of internal and external data, including FDA data, our compliance team is working to identify more quickly potential risks, trends, and themes. Using the analyses, we will work proactively to deliver or implement alerts, controls, training, or monitoring to reduce further the risk of an underage sale.

What is more, at Walmart and Sam's Club, we are voluntarily making two significant changes to our product offerings and business practices, both aimed at reducing the likelihood of an underage sale—and both of which go beyond what the law requires. First, we are in the process of discontinuing the sale of fruit- and dessert-flavored electronic nicotine delivery systems (ENDS), which your research has shown to be preferred by minors. Second, as of July 1, 2019, across our entire U.S. business, we are raising the minimum age to purchase tobacco products, including ENDS, to 21.

We unequivocally acknowledge that even a single sale of a tobacco product to a minor is one too many, and we take seriously our responsibilities in this regard. The FDA can be assured that we will remain focused on improving our compliance program and rates and that any sale-to-minor violation will be handled promptly and appropriately—and viewed not as a cost of doing business but as a breach of trust with the customers and communities we serve. Our sincere intent and hope are that the changes outlined in this letter will have a substantial public health impact by helping to keep tobacco products out of the hands of minors.

We of course welcome your feedback and input regarding the above steps and are available at your convenience to address any questions or concerns.

Sincerely,



John Scudder
U.S. Chief Ethics & Compliance Officer
Walmart Inc.
John.Scudder@walmart.com

cc: Jill Atencio, FDA, Division of State Programs Center for Tobacco Products (via e-mail)