

FDA pursues order barring specific retailers from selling tobacco products as part of its continuing efforts to target youth tobacco use

 [fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm630913.htm](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm630913.htm)

Statement

The U.S. Food and Drug Administration today initiated enforcement action against certain retail locations of Walgreen Co. and Circle K Stores Inc. for repeated violations of restrictions on the sale and distribution of tobacco products, including sales of cigars and menthol cigarettes to minors. The agency filed complaints seeking No-Tobacco-Sale Orders (NTSO), which seek to bar the two specific retail locations from selling tobacco products for 30 days. The two retail outlets that are the subject of these NTSO actions are a Walgreens store in Miami, Florida, and a Circle K store in Charleston, South Carolina. Notably, Walgreens is currently the top violator among pharmacies that sell tobacco products, with 22 percent of the stores inspected having illegally sold tobacco products to minors.

“I will be writing the corporate management of Walgreens and requesting a meeting with them to discuss whether there is a corporate-wide issue related to their stores’ non-compliance and put them on notice that the FDA is considering additional enforcement avenues to address their record of violative tobacco sales to youth. We all share the important responsibility of keeping harmful and addictive tobacco products out of the hands of kids. Retailers in particular – especially those who position themselves as health-and-wellness-minded businesses – are on the frontlines of these efforts and must take that legal obligation seriously. I’m also deeply disturbed that a single pharmacy chain racked up almost 1,800 violations for selling tobacco products to minors across the country. I have particular concerns about whether the pharmacy setting is influencing consumer and retailer perceptions around tobacco products in a way that’s contributing to these troubling findings,” said FDA Commissioner Scott Gottlieb, M.D. “The FDA will continue to hold retailers accountable by vigorously enforcing the law. We are also evaluating our data on other large, national retail chains to identify other entities that also have high rates of repeat violations and are considering what additional measures we should pursue. While many of our recent enforcement actions focused on the illegal sales and marketing of e-cigarettes, today’s announcement is a reminder that youth access to all tobacco products remains a public health problem. No child should be using any tobacco or nicotine-containing product. And no retailer should be illegally selling these products to minors. As part of our Youth Tobacco Prevention Plan, we’ll continue to employ all the tools at our disposal to monitor, penalize and prevent sales of all tobacco products, including e-cigarettes, to minors at brick-and-mortar stores and Internet storefronts as we work to ensure these products are sold in ways that make them less accessible and appealing to kids.”

An estimated 4.9 million middle and high school students reported current (past 30 days) use of any tobacco product in 2018, according to preliminary results of the 2018 National Youth Tobacco Survey. An epidemic-level rise in e-cigarette use over the last year has led overall tobacco product use to increase by 38 percent among high school students (to 27.1 percent) and by 29 percent among middle school students (to 7.2 percent) in the last year, reversing the declines seen in the last few years.

Because tobacco use is almost always initiated and established during adolescence, early intervention – including making sure tobacco products aren't being sold to kids – is critical. One of the ways the FDA combats youth tobacco use is through its compliance and enforcement efforts. In particular, the agency provides education and training opportunities to retailers to encourage compliance with restrictions on sales to minors, monitors compliance through surveillance, inspections and investigations, and then takes action when violations occur.

When violations are found, the agency generally issues warning letters and may take enforcement actions, including civil money penalties and NTSOs. Since its retailer enforcement program began in 2010, the FDA has issued more than 81,570 warning letters to retailers for violating the law, initiated more than 19,800 civil money penalty cases and issued 145 NTSOs, as of Dec. 31, 2018.

The NTSO action against this Walgreens outlet follows the issuance of more than 1,550 warning letters and 240 civil money penalty actions against Walgreens stores nationwide for unlawful tobacco product sales to minors. This is, however, the first NTSO action taken against a Walgreens store. While the NTSO action against Circle K is not its first, it marks the first time the agency has initiated an NTSO complaint for the sale of deemed products (cigars) to minors. Since 2010, the FDA has issued over 1,045 warning letters and 205 civil money penalty actions to retailers doing business as Circle K for sales to minors. To put Walgreens' rate of violations into perspective, among other national, corporate-owned chains, 17.5 percent of Walmart Inc. stores inspected had violations for illegal sales of tobacco products to minors. Additionally, 14 percent of Dollar General Corp. stores inspected, and 9.6 percent of Rite Aid Corp. stores inspected had illegally sold tobacco products to minors.

Under the law, the FDA may pursue an NTSO against a retail outlet that has committed a total of five or more repeated violations of federal tobacco regulations within 36 months. After the FDA initiates an NTSO action by filing a complaint, a retailer has the opportunity to respond to the complaint, and must generally do so within 30 days. Retailers who receive an NTSO complaint from the FDA may enter into a settlement agreement or respond with an answer and contest the allegations before an administrative law judge. If an NTSO goes into effect, a retailer is responsible for ensuring that the establishment does not sell tobacco products during the specified period. Removing or covering up tobacco products are examples of steps that a retailer may choose to take to ensure compliance with an NTSO, but these specific actions are not required. It is up to the retailer to decide what measures to take to ensure no regulated tobacco products are sold at the store during the time period specified in the order. The FDA plans to conduct unannounced compliance check inspections during that period to

check whether each establishment is complying with the terms of the order and will take further action if necessary. Consumers and other interested parties can report a potential tobacco-related violation of the Food Drug & Cosmetic Act, including sale of tobacco products to minors, by using the [FDA's Potential Tobacco Product Violation Reporting Form](#).

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.