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September 12, 2018

Mr. Mark Langer, Clerk of the Court
Office of the Clerk
U.S. Court of Appeals for the D.C. Circuit
333 Constitution Ave., NW
Washington, DC 20001

Re: *Nicopure Labs, LLC v. FDA*, No. 17-5196 (oral argument heard Sept. 11, 2018)

Dear Mr. Langer:

At yesterday's oral argument, we informed the Court that FDA has recently taken enforcement actions as part of an effort to prevent use of e-cigarettes by youth. Today, the FDA Commissioner announced significant new actions designed to address "an epidemic of e-cigarette use among teenagers." Statement from FDA Commissioner Scott Gottlieb (Sept. 12, 2018).

As part of its enforcement discretion, FDA previously extended the compliance date for premarket product review for certain newly deemed e-cigarette products until 2022. These products were required to have premarket review as of the effective date of FDA's deeming rule in 2016, and have been marketed only by virtue of such enforcement discretion since that time.

As described in today's statements, FDA is reconsidering the extended compliance dates for the submission of new product applications when it is apparent that there is widespread youth use of the product, and is also considering a policy change that would lead to immediate removal of flavored e-cigarette products from the market.

This summer, FDA undertook an intensive nationwide initiative to detect the illegal sale of e-cigarettes to minors by stores. Today, FDA sent letters to five e-cigarette manufacturers whose products were sold to minors during the agency's enforcement blitz, and which collectively represent more than 97 percent of the e-cigarette market. FDA has indicated that the manufacturers should come to FDA in 60 days with robust plans to address the widespread use of their products by minors, and that FDA may otherwise revisit its exercise of enforcement discretion for products currently on the market. FDA also issued more than 1,300 warning letters and civil money penalty complaints (fines) to retailers that illegally sold e-cigarettes during the intensive enforcement campaign.

Today's press statements are attached to this letter.[1] These actions complement but cannot replace other tools Congress provided to address the dangers of tobacco products. The modified-risk tobacco products provision, for instance, requires manufacturers to substantiate health-related claims they wish to make about their products before they market these addictive products to consumers as presenting reduced health risks.

Sincerely,

s/ Tyce R. Walters
TYCE R. WALTERS

cc: All counsel by ECF

[1] They are also available, along with the letters, at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm; https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620184.htm.

CERTIFICATE OF SERVICE

I hereby certify that on September 12, 2018, I electronically filed the foregoing letter with the Clerk of the Court by using the appellate CM/ECF system. I further certify that the participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Tyce R. Walters
Tyce R. Walters

FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use

For Immediate Release

September 12, 2018

Statement

More than a year ago, the FDA unveiled a broad policy to reduce the death and disease caused by smoking. Smoking remains the number one preventable cause of death in America, killing nearly half a million people a year. If we aren't successful in more sharply reducing the rate of addiction to tobacco, then we'll continue to see this needless death and disease. FDA's new legal authorities to regulate tobacco – as part of the Tobacco Control Act – empowered us to alter this trajectory.

We saw an opening to push a generational shift in the deadly course caused by tobacco. And we've seized it.

Our comprehensive tobacco plan to combat the ill effects of smoking was founded on a central animating principle. That what primarily causes death and disease from tobacco use isn't the nicotine in these products. It's the act of lighting tobacco on fire to free that drug for inhalation.

While it's the addiction to nicotine that keeps people smoking, it's primarily the combustion, which releases thousands of harmful constituents into the body at dangerous levels, that kills people.

This fact represents both the biggest challenge to curtailing cigarette addiction – and also holds the seeds of an opportunity that's a central construct for our actions.

E-cigarettes may present an important opportunity for adult smokers to transition off combustible tobacco products and onto nicotine delivery products that may not have the same level of risks associated with them. So, we set out on a new rulemaking process that seeks to regulate the nicotine levels in combustible cigarettes to render them minimally or non-addictive. That process is well underway.

And at the same time, we're developing a path to properly regulate non-combustible forms of nicotine delivery, like electronic cigarettes, that may be an alternative for adults who still want to get access to satisfying levels of nicotine, without all the risks associated with lighting tobacco on fire.

We saw an important opportunity. We saw a chance to leverage the potential benefits of new and non-combustible technology to allow more adults to get nicotine from sources that could pose a lot less harm than smoking cigarettes. We continue to believe in this central concept.

But let me be clear that nicotine isn't a benign substance. This is especially true when it comes to children, and the effects that nicotine has on a developing brain. That's why we need a strong regulatory process that puts these new products through an appropriate series of regulatory gates.

We need a regulatory process that requires product applications to show that the marketing of the product is appropriate for the protection of the health of the overall population. And we need a regulatory process that keeps these same electronic cigarette products out of the hands of youth.

This is our current policy framework to fulfill a central premise of our public health mandate.

We need to make sure that we properly evaluate the net public health impact of products like e-cigs before they get marketing authorization from the FDA and that these products meet their regulatory responsibilities. Such products may still pose health risks, including possibly releasing some chemicals at higher levels than conventional cigarettes, and these potential risks require closer scrutiny.

But since electronic nicotine delivery system (ENDS) products had only been recently brought under FDA's regulatory jurisdiction, few of the foundational rules and guidance documents for defining and clarifying the premarket authorization process for such products had been established at the time I joined the FDA 17 months ago. So, to create this regulatory framework for how we'd properly evaluate the electronic nicotine delivery products, we've committed to the development of guidance and regulations, including product standards, that will better spell out the rules of the road. And we're making significant progress toward achieving these procedural goals.

If we succeed in our overall plan, the public health impact can dwarf anything else we're able to accomplish in any reasonable stretch of time. It can dwarf the introduction of any new medical technology. Analysis shows that our plan has the potential to drop smoking rates from the current 15 percent to as low as 1.4 percent. It can prevent more than 33 million people – including children – from becoming smokers; avoiding a lot of the death and disease that's going to be caused by cigarettes. Yet despite our progress, and these metrics, we find ourselves at a very challenging crossroads in the execution of this plan.

That's because we didn't foresee the extent of what's now become one of our biggest challenges. We didn't predict what I now believe is an epidemic of e-cigarette use among teenagers. Today we can see that this epidemic of addiction was emerging when we first announced our plan last summer. Hindsight, and the data now available to us, reveal these trends. And the impact is clearly apparent to the FDA.

Unfortunately, I now have good reason to believe that it's reached nothing short of an epidemic proportion of growth.

I use the word epidemic with great care. E-cigs have become an almost ubiquitous – and dangerous – trend among teens. The disturbing and accelerating trajectory of use we're seeing in youth, and the resulting path to addiction, must end. It's simply not tolerable. I'll be clear. The FDA won't tolerate a whole generation of young people becoming addicted to nicotine as a tradeoff for enabling adults to have unfettered access to these same products.

This fundamental commitment is why FDA launched our Youth Tobacco Prevention Plan earlier this year.

That plan encompassed a series of actions to stop youth use of tobacco products, especially the rising use of e-cigarettes. Our Youth Tobacco Prevention Plan focuses on three key strategies. First, preventing youth access to tobacco products. Second, curbing the marketing of tobacco products aimed at youth. And finally, educating teens about the dangers of using any tobacco products.

Recognizing that our most immediate tool to address youth use is enforcement, this has been a cornerstone of our approach. And it's a tool that we'll continue to deploy, and with growing vigor, to directly address this challenge.

We've taken a series of compliance actions over the past year. In partnership with the Federal Trade Commission, we targeted misleadingly labeled or advertised e-liquids resembling kid-friendly foods like juice boxes, candy and cookies. Since then, the manufacturers, distributors, and retailers that were warned by the FDA have stopped selling products with the offending labeling and advertising. And, today, the FDA issued 12 warning letters to other companies that continue to advertise and sell the violative products. This includes several companies that are also cited by the FDA for illegally selling the products to kids.

We've also sharply expanded our enforcement against retailers who illegally sell e-cigarettes to kids.

This spring, we focused on sales of JUUL, issuing 56 warning letters and six civil monetary penalties to retailers as part of this effort. And, today, we're announcing that we're taking other, significant enforcement and compliance actions.

We're announcing the largest ever coordinated initiative against violative sales in the history of the FDA. This is the largest single enforcement action in agency history. It's aimed at retail and online sales of e-cigarettes to minors.

We sent more than 1,100 warning letters to stores for the illegal sale of e-cigarettes to minors. In addition, we issued another 131 civil money penalties to stores that continued to violate the restrictions on sales to minors.

But we must do more to stem what I see as an epidemic of use of e-cigs among teens, and deeply disturbing trends that show no sign of abating. So, we're also going to re-visit the compliance policy that we announced last summer to extend the application compliance periods for certain deemed products, including and especially the e-cigarettes that were on the market as of Aug. 8, 2016. Under the current policy, the compliance date for filing applications for such products was extended to Aug. 8, 2022.

We exercised that discretion for ENDS products because, as part of the tobacco and nicotine regulatory framework that we developed, which includes pathways to transition smokers off combustible cigarettes, we wanted to allow time for FDA to establish and more clearly explain the series of appropriate regulatory gates – and for companies to prepare quality applications for new products like e-cigarettes. That's where the e-cigarettes and other non-combustible products come into play. We wanted to make sure – before we began enforcement of the application requirements – that there was a clear, viable pathway to seek FDA authorization to market alternative products for adult smokers who still sought access to nicotine.

But in view of the accelerating use among youth, we're actively considering whether we will enforce the premarket review provision earlier, when it is apparent that these products are now subject to widespread youth use.

One factor we're closely evaluating is the availability of characterizing flavors. We know that the flavors play an important role in driving the youth appeal. And in view of the trends underway, we may take steps to curtail the marketing and selling of flavored products. We're now actively evaluating how we'd implement such a policy.

I've spent a lot of time considering whether there were different choices we could have made last summer that would have lessened, or avoided, the epidemic of youth use that I believe is before us. As stewards of public health, this is an important question that we must ask ourselves as we consider what steps to take at this challenging crossroads.

For instance, what if we hadn't extended the compliance dates for filing applications for e-cigs on the market when the deeming rule went into effect? In reality, most of those applications wouldn't have been submitted until last month. And the e-cigs would have remained on the market for at least an additional year while we reviewed them. So, products would've still been on the market, and we might still have had the disturbing trends gripping us now in 2018.

When we set that comprehensive plan in motion, we also knew we didn't have all the regulations and guidance that we wanted in place to more clearly define the application pathway for these non-combustible alternatives. While the statute places the burden on manufacturers to show with scientific evidence that the public health standards in the law are met, we also understood that many manufacturers were new to regulation. And many novel products were already on the market. Given the circumstances, we felt that it was important to provide clear, transparent, and predictable rules of the road for industry. And so, for these reasons, we wanted to give the e-cig industry time to come into compliance while we wrote the guidance and regulations to better define and explain how the new products would meet those application requirements. It was an exercise in good government that was taken to accommodate the continued availability of innovations that we believe have potential value.

But our public health mandate to prevent youth addiction has forced us to now revisit this element of our overall plan.

The legal standard for FDA premarket review of a new tobacco product includes consideration of whether the product would be appropriate for the protection of the public health. We must factor in whether these products get kids addicted to nicotine. It's that simple. And we are taking aggressive actions today to address this.

This may create some obstacles for some adults who also enjoy e-cigs. These are the hard tradeoffs that we're grappling with. But the youth risk is paramount.

It's now clear to me, that in closing the on-ramp to kids, we're going to have to narrow the off-ramp for adults who want to migrate off combustible tobacco and onto e-cigs.

This isn't our choice alone.

I've been warning the e-cigarette industry for more than a year that they needed to do much more to stem the youth trends. In my view, they treated these issues like a public relations challenge rather than seriously considering their legal obligations, the public health mandate, and the existential threat to these products. And the risks mounted.

Well, I'm here to tell them that this prior approach is over. The FDA is closely watching the trends in youth use. And if, as we expect, preliminary data that's in our possession and will be finalized and released in the coming months confirm our present observations that the youth use of e-cigs is rising very sharply; we'll swiftly change course.

In the meantime, the FDA is announcing an escalating series of actions to forcefully address youth use trends.

It starts with the steps that we're taking today, with the announcement of the largest coordinated tobacco compliance effort in FDA's history.

In addition, as I noted, we're seriously reconsidering our compliance dates for the submission of product applications when it is apparent that there's widespread youth use of the product. We're especially focused on the flavored e-cigarettes. And we're seriously considering a policy change that would lead to the immediate removal of these flavored products from the market.

Today, we sent letters to five e-cigarette manufacturers whose products were sold to kids during the enforcement blitz and that, collectively, represent more than 97 percent of the current market for e-cigs — JUUL, Vuse, MarkTen, blu e-cigs, and Logic. These brands will be the initial focus of our attention when it comes to protecting kids.

They're now on notice by the FDA of how their products are being used by youth at disturbing rates.

Given the magnitude of the problem, we're requesting that the manufacturers of these brands and products come back to the FDA in 60 days with robust plans on how they'll convincingly address the widespread use of their products by minors, or we'll revisit the FDA's exercise of enforcement discretion for products currently on the market.

Let me be clear. This may require these brands to revise their sales and marketing practices, including online sales; to stop distributing their products to retailers who sell to kids; and to remove some or all of their flavored e-cig products from the market until they receive premarket authorization and otherwise meet applicable requirements.

In the meantime, we'll be investigating their marketing and sales practices, including with boots on the ground inspections. The FDA is going to continue to work to find out why so many kids are using and abusing these products.

And we're not going to stop there.

We're also re-examining the enforcement discretion we currently exercise for other e-cig products currently on the market without authorization. Today's letters target the five dominant e-cig manufacturers, including those whose products were purchased by kids in our enforcement blitz. But the policy reconsiderations apply to the entire category.

As we do this, we're considering how the different products are being used by kids. The biggest youth use seems to be among cartridge-based e-cigarettes, and not the open-tank vaping products. So, we're exploring policy options that could let us adjust the policy steps we take to account for different product use patterns between kids and adults. Our focus is on the products that are being misused by minors.

We're also going to permanently step up our enforcement actions with a sustained campaign to monitor, penalize and prevent e-cig sales to minors in convenience stores and other retail sites. It's clear there's need for strong federal enforcement of youth access restrictions.

We'll continue to hold retailers accountable by vigorously enforcing the law with the help of our state partners. The e-cig manufacturers ought to follow suit. They should also ensure that their online sales are not part of the problem.

Although today's action included warning letters for online sales, following up on our retail blitz, we're taking a hard look at the manufacturer's own internet storefronts and distribution practices. We'll look at whether internet sites are being used to make straw purchases with the intent for redistribution to minors. If young adults go online and buy 100 units of a product to sell to teens, that activity ought to be easy for a product manufacturer to identify, and FDA will consider what steps we can take in these circumstances.

Let me be clear: Everything is on the table. This includes the resources of our civil and criminal enforcement tools.

If the companies don't know, or if they don't want to know, that straw purchases are occurring, we'll now be helping to identify it for them. If violative activities are found, the FDA has both civil and criminal remedies at its disposal.

We are also investigating whether makers of certain e-cig products may be subject to enforcement for marketing new products that don't have pre-market authorization and were introduced after the FDA's compliance date.

And next week, we're also announcing a national campaign to warn teenagers of the dangers of nicotine and e-cigarette use. This public campaign will bring these public health messages to online sites that we know teenagers access, and even to high school bathrooms.

I challenge e-cig manufacturers to take equally bold action to reform their own practices. There's some historical advertising that I've seen, especially on social media, that gives me pause as to how earnest some of these companies were in making sure that kids didn't use their products.

As I noted earlier, we'll also be taking steps beyond compliance and enforcement. We plan to update our recommendations that lay out the Pre-Market Tobacco Product application pathway and the evidence we expect to see when manufacturers file those applications. We believe there's no excuse for manufacturers not to file applications with the FDA because the agency hasn't told

them what they are expected to do. If any manufacturer wants to get direct, precise guidance on a specific product application, just call us. Request a meeting. Our door is open. And our policy is to grant pre-submission meetings to help manufacturers understand our expectations.

The staff of our Center for Tobacco Products is also working on an overall policy roadmap to address these trends, while remaining true to the goals of our comprehensive plan announced last summer, and to the public health purpose that animates our work every day. They'll be presenting to me a strengthened approach, building on our Youth Tobacco Prevention Plan, to address the rising use of e-cigs by minors. I'll communicate the additional decisions that we make together as an agency in a timely fashion.

The steps I'm announcing today are the initial elements of these new efforts that we're committing to right away. I believe there's an epidemic of youth use. We have good reason to draw this conclusion based on the trends and data that we've seen, some of which is still preliminary and will be finalized in the coming months and presented publicly. But our actions today are firmly rooted in what we've learned. There's no mistaking the risks.

At the FDA, we still believe that new innovations that don't use combustion, like the electronic cigarettes, offer an important opportunity for adults to transition off combustible tobacco. I still believe in this opportunity. I still believe in the concept of modified risk products. I still believe that tobacco products exist on a continuum of risk, and that there are opportunities to move adult smokers down that ladder of harm. The leadership of the FDA's tobacco center still firmly believes in this concept.

And we're all committed to helping reduce the overall burden of risk to our nation.

We're committed to the purpose of harm reduction.

We're committed to saving lives. And we're committed to changing the trajectory of death and disease from tobacco.

We started to confront these trends right out of the gate with the comprehensive tobacco policy that we announced last summer. We ramped up these efforts with the announcement of our Youth Tobacco Prevention Plan last spring. And today, we're taking a new turn in our efforts as youth trends worsen. We'll bend that trajectory on this growing youth addiction. We must succeed. But we're not the only party to this problem.

Industry must step up to this challenge. The companies selling the brands that resulted in the most illegal sales in our enforcement blitz have 60 days to respond with forceful plans of their own or face regulatory consequences.

They say they've changed from the days of Joe Camel. But look at what's happening right now, on our watch and on their watch. They must demonstrate that they're truly committed to keeping these new products out of the hands of kids and they must find a way to reverse this trend.

I believe in the power of American ingenuity to solve a lot of problems, including this one. I'm deeply disturbed by the trends I've seen. I'm disturbed by an epidemic of nicotine use among teenagers. So, we're at a crossroads today. It's one where the opportunities from new innovations will be responsibly seized on right now, or perhaps lost forever.

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.

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FDA News Release

FDA takes new steps to address epidemic of youth e-cigarette use, including a historic action against more than 1,300 retailers and 5 major manufacturers for their roles perpetuating youth access

Warning letters and civil money penalty complaints to retailers are largest coordinated enforcement effort in agency history; FDA requests manufacturers provide plan for mitigating youth sales within 60 days; warns it may restrict flavored e-cigarettes to address youth epidemic

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For Immediate Release

September 12, 2018

Release

The U.S. Food and Drug Administration today announced a series of critical and historic enforcement actions related to the sale and marketing of e-cigarettes to kids. In the largest coordinated enforcement effort in the FDA's history, the agency **issued (/TobaccoProducts/NewsEvents/ucm605278.htm)** more than 1,300 warning letters and civil money penalty complaints (fines) to retailers who illegally sold JUUL and other e-cigarette products to minors during a nationwide, undercover blitz of brick-and-mortar and online stores this summer. As a result of these violations of the law – and other indications that e-cigarette use among youth has hit epidemic proportions – FDA Commissioner Scott Gottlieb, M.D., signaled that the agency intends to take new and significant steps to address this challenge **in a speech (/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm)** at the agency's headquarters.

"We're committed to the comprehensive approach to address addiction to nicotine that we announced last year. But at the same time, we see clear signs that youth use of electronic cigarettes has reached an epidemic proportion, and we must adjust certain aspects of our comprehensive strategy to stem this clear and present danger. This starts with the actions we're taking today to crack down on retail sales of e-cigarettes to minors. We will also revisit our compliance policy that extended the dates for manufacturers of certain flavored e-cigarettes to

submit applications for premarket authorization. I believe certain flavors are one of the principal drivers of the youth appeal of these products. While we remain committed to advancing policies that promote the potential of e-cigarettes to help adult smokers move away from combustible cigarettes, that work can't come at the expense of kids. We cannot allow a whole new generation to become addicted to nicotine. In the coming weeks, we'll take additional action under our Youth Tobacco Prevention Plan to immediately address the youth access to, and the appeal of, these products," said FDA Commissioner Gottlieb. "Today, we asked five e-cigarette manufacturers to put forward plans to immediately and substantially reverse these trends, or face a potential decision by the FDA to reconsider extending the compliance dates for submission of premarket applications. Our comprehensive plan on nicotine and tobacco regulation remains intact and we remain committed to its goals to reduce tobacco-related disease and death, including our efforts to reduce the nicotine in combustible products to render cigarettes minimally or non-addictive. We're also fully committed to the concept that products that deliver nicotine exist on a continuum of risk, with combustible products representing the highest risk, and electronic nicotine delivery systems perhaps presenting an alternative for adult smokers who still seek access to satisfying levels of nicotine, but without all of the harmful effects that come from combustion. But in enabling a path for e-cigarettes to offer a potentially lower risk alternative for adult smokers, we won't allow the current trends in youth access and use to continue, even if it means putting limits in place that reduce adult uptake of these products."

FDA undertakes aggressive enforcement strategy targeting illegal sales to youth and kid-friendly marketing

As part of the agency's **Youth Tobacco Prevention Plan (/TobaccoProducts/PublicHealthEducation/ProtectingKidsfromTobacco/ucm608433.htm)** and ongoing work to protect youth from the dangers of tobacco products, the FDA has taken a series of actions over the past several months to more immediately target the illegal sales of e-cigarettes to youth, as well as the kid-friendly marketing and appeal of these products.

The FDA is stepping up those efforts indefinitely.

One aspect of the agency's plan will entail increased enforcement. The more than 1,300 warning letters and fines to retailers announced today were part of a large-scale, undercover nationwide blitz to crack down on the sale of e-cigarettes to minors at both brick-and-mortar and online retailers, which was conducted from June through the end of August. The vast majority of the violations were for the illegal sale of five e-cigarette products – Vuse, Blu, JUUL, MarkTen XL, and Logic. These five brands currently comprise over 97 percent of the U.S. market for e-cigarettes.

In addition, today the FDA also **issued 12 warning letters (/ICECI/EnforcementActions/WarningLetters/default.htm)** to other online retailers that are selling misleadingly labeled and/or advertised e-liquids resembling kid-friendly food products such as candy and cookies. These products were the subject of **agency action in May (/TobaccoProducts/NewsEvents/ucm605729.htm)** and, subsequently, are **no longer being sold (/NewsEvents/Newsroom/PressAnnouncements/ucm618169.htm)** with the offending labeling and advertising by the companies that received the May warning letters. However, the retailers receiving the warning letters today are still advertising and selling the violative products. Several of these retailers were also cited for illegally selling the products to minors. The agency will continue to monitor and take action against companies that sell tobacco products that might mislead a young child into thinking the product is appropriate for them to consume as food. The FDA has more compliance actions underway.

In addition to these new actions, the FDA had **previously issued (/TobaccoProducts/NewsEvents/ucm605278.htm)** more than 60 warning letters and fines to businesses that sold JUUL brand products to minors stemming from another enforcement blitz this past spring. The agency also recently sent letters to **JUUL Labs (/NewsEvents/Newsroom/PressAnnouncements/ucm605432.htm)** and **several other companies (/NewsEvents/Newsroom/PressAnnouncements/ucm607935.htm)** requiring them to submit important documents to better understand the reportedly high rates of youth use and the particular youth appeal of their products. The FDA is currently investigating whether manufacturers introduced certain e-cigarette products to the market after Aug. 8, 2016, and may be subject to enforcement for marketing those products without premarket authorization.

The FDA also continues to conduct checks of retail establishments that sell tobacco products to ensure compliance with federal laws. In total, the FDA has conducted 978,290 retail inspections, issued 77,180 warning letters to retailers for violating the law and initiated approximately 18,560 civil money penalty cases, as of Sept. 1, 2018. There is a clear need for strong federal enforcement of youth access restrictions and the FDA will continue to hold retailers accountable by vigorously enforcing the law with the help of the agency's state partners.

The agency also has issued more than 135 No-Tobacco-Sale Order Complaints, which can result in retailers being prohibited from selling tobacco products for specified periods of time.

FDA warns youth use of e-cigarettes is reaching epidemic proportions, signals new, aggressive steps to address challenge, including re-examining FDA's compliance policy regarding flavored e-cigarettes

Over the past several years, e-cigarettes were the most commonly used tobacco product by youth. In fact, **more than 2 million middle and high school students (/TobaccoProducts/PublicHealthEducation/ProtectingKidsfromTobacco/ucm405173.htm)** were current users of e-cigarettes in 2017.

This use by children and teens is especially concerning to the FDA because the developing adolescent brain is particularly vulnerable to nicotine addiction. That's why combating youth use of nicotine-containing products is a core priority and the guiding principle behind the FDA's Youth Tobacco Prevention Plan.

The FDA now believes that youth use of e-cigarettes is reaching epidemic proportions. This belief is based on not just the results of the agency's enforcement actions, but also recent sales trends, news coverage, increased concerns among kids, parents and educators, as well as preliminary data that will be finalized and released in the coming months.

To address these trends, and as another part of the agency's effort, the FDA is re-examining its compliance policy dates for the submission of premarket tobacco applications to the FDA for certain e-cigarettes. Toward these goals, and recognizing the critical role manufacturers must play in curtailing youth use of their products, the FDA today **issued letters (/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm281784.htm)** to the manufacturers of the five top-selling national brands. All of these brands – JUUL, Vuse, MarkTen XL, blu e-cigs, and Logic – made up a vast majority of the products illegally sold to minors as part of the blitz this summer. The agency is asking each company to submit to FDA within 60 days plans describing how they will address the widespread youth access and use of their products. If they fail to do so, or if the plans do not appropriately address this issue, the FDA will consider whether it would be appropriate to revisit the current policy that results in these products remaining on the market without a marketing order

from the agency. This could mean requiring these brands to remove some or all of their flavored products that may be contributing to the rise in youth use from the market until they receive premarket authorization and otherwise meet all of their obligations under the law.

Today, the agency has also committed to taking even stronger measures to stem these troubling trends of youth use:

- Looking at, and potentially changing, the FDA's current compliance policy to determine whether it can better account for manufacturers that are not successfully preventing widespread youth use of their products. This means re-examining all aspects of the enforcement discretion that the FDA exercised when it extended the compliance dates for premarket authorization for certain newly deemed tobacco products. This could also mean revising the overall policy that applies to all manufacturers, which would go beyond the requests that were sent with respect to certain individual products today, and address the entire category of cartridge based e-cigarettes.
- Indefinitely stepping up FDA enforcement actions with a sustained campaign to monitor, penalize and prevent e-cigarette sales in convenience stores and other retail sites.
- Closely evaluating manufacturers' own internet storefronts and distribution practices and taking appropriate enforcement actions if we find violations of the restrictions on sales to minors. The FDA has at its disposal both civil and criminal remedies to address demonstrated violations of the law.
- Investigating whether manufacturers of certain e-cigarette products may be marketing new products that were not on the market as of Aug. 8, 2016, thus falling outside of the FDA's compliance policy, and have not gone through premarket review.

The FDA will also be developing an overall policy roadmap, designed to both address these trends and remain true to the goals of the **comprehensive plan on nicotine and tobacco regulation (/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm)** announced in July 2017, which aims to render cigarettes minimally or non-addictive and encourage the development of innovative tobacco products that could help currently addicted adult smokers switch to potentially less harmful forms of nicotine delivery. This also includes new steps that the FDA will announce in the coming weeks to promote wider access to nicotine replacement therapy marketed as new drugs as a way to help more adult smokers quit cigarettes.

As part of the FDA's comprehensive plan, the agency also continues to explore clear and meaningful measures to make tobacco products less toxic, appealing and addictive with an intense focus on youth. This could include measures on flavors/designs that appeal to youth, child-resistant packaging and product labeling to prevent accidental child exposure to liquid nicotine. The FDA also issued an **advance notice of proposed rulemaking (/NewsEvents/Newsroom/PressAnnouncements/ucm601690.htm)** in March to seek public comment on the role that flavors in tobacco products play in attracting youth. Additionally, the agency plans to explore additional restrictions on the sale and promotion of ENDS to further reduce youth exposure and access to these products.

The FDA has also **expanded "The Real Cost" public education campaign (/NewsEvents/Newsroom/FDAInBrief/ucm581312.htm)** with messages focused on preventing youth use of e-cigarettes. The FDA will launch a new, full-scale e-cigarette campaign targeted to youth next week.

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.

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Related Information

- Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use (/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm)
- FDA's Youth Tobacco Prevention Plan (/TobaccoProducts/PublicHealthEducation/ProtectingKidsfromTobacco/ucm608433.htm)
- Warning Letters and Civil Money Penalties Issued to Retailers for Selling JUUL and Other E-Cigarettes to Minors (/TobaccoProducts/NewsEvents/ucm605278.htm)
- CTP Letters to Industry (/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm281784.htm)
- Public Health Education Campaigns (/TobaccoProducts/PublicHealthEducation/PublicEducationCampaigns/default.htm)

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