


Today was a bad day for e-cigarettes and flavored tobacco products generally, particularly JUUL

 tobacco.ucsf.edu/today-was-bad-day-e-cigarettes-and-flavored-tobacco-products-generally-particularly-juul

There has been growing public concern about the explosive growth of flavored tobacco products, particularly the explosive growth of JUUL e-cigarettes among kids.

Public health responded today on both coasts.

The California Department of Public Health launched a brilliant (and colorful) educational effort on the impact of flavored tobacco products on kids. You can see the TV ads on “the tobacco industry’s kids menu” [here](#). At least two of the ads, [Fruit Candy](#) and [Bedroom](#) feature JUUL. The accompanying web page <https://www.flavorshookkids.org/> gives loads of great information and shows the print ads.

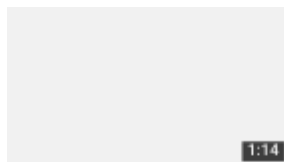


I never cease to be amazed at how talented CDPH and their ad agency [Duncan Channon](#) are at taking complicated science and tobacco industry behavior and boiling them down to compelling messages that people can understand.

Meanwhile, back on the East Coast, the [FDA announced a crackdown on e-cigarette marketing directed at kids](#). In what FDA characterized as “the first steps in a new effort aimed at stopping youth use of e-cigarettes,” [FDA wrote JUUL](#) demanding extensive information on how the product works and how it is marketed.

Beyond the immediate effects on making and marketing products to kids, the information these efforts turn up is likely to make it crystal clear that flavors are for kids and that marketing e-cigs as widely available consumer products for adults without pulling in kids is all but impossible.

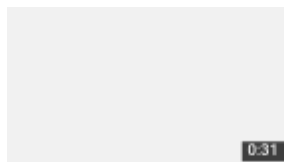
Overall, a good day for public health.



1:14

Kids and the Tobacco Predator - Tobacco Free CA

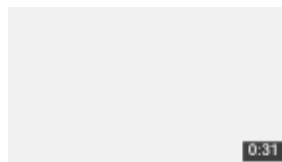
TobaccoFreeCA
21,136 views • 3 years ago



0:31

Kids and the Tobacco Predator

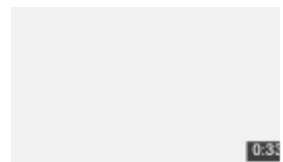
TobaccoFreeCA
6,382 views • 2 years ago



0:31

Ninos y Tabaco

TobaccoFreeCA
720 views • 2 years ago



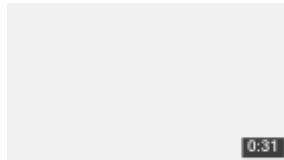
0:31

Kids and the Tobacco Predator - Vietnamese

TobaccoFreeCA
358 views • 1 year ago

Environment and Tobacco

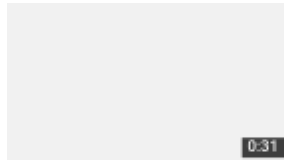
Learn how tobacco negatively impacts the environment.



0:31

"Just A Cig" :30 TV

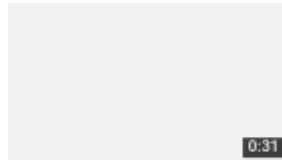
TobaccoFreeCA
844 views • 9 months ago



0:31

"Literally" :30 TV

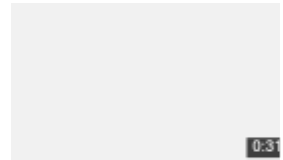
TobaccoFreeCA
1,445 views • 9 months ago



0:31

"It's Time" :30 Radio

TobaccoFreeCA
223 views • 9 months ago

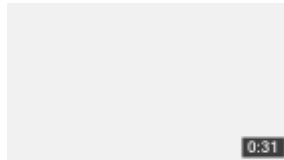


0:31

"Who Knew?" :30 Radio

TobaccoFreeCA
185 views • 9 months ago

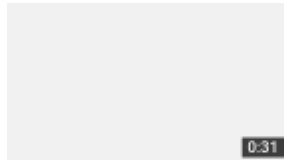
Secondhand & Thirdhand Smoke



0:31

"Apartment" :30 TV

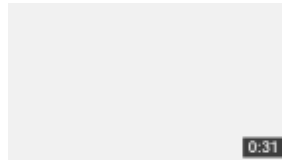
TobaccoFreeCA
2,212 views • 5 months ago



0:31

"Secondhand Sally" :30 TV

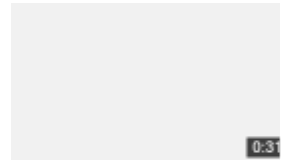
TobaccoFreeCA
4,656 views • 5 months ago



0:31

"Coughing" :30 Spanish Radio

TobaccoFreeCA
112 views • 3 months ago

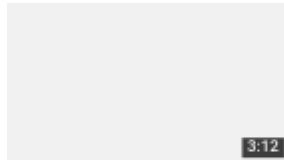


0:31

"Coughing" :30 Radio

TobaccoFreeCA
156 views • 3 months ago

Popular uploads

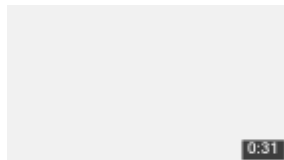


3:12

Real California teens talk about vaping.

1 year ago • 401,672 views

Real California teens talk about their real experiences with vaping. If you think adults are the only ones getting hooked on vaping, it's time to WAKE UP at <http://stillblowingsmoke.org>. Lik...

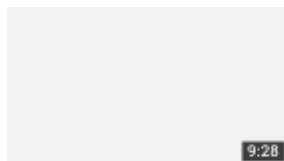


0:31

Debi Austin "Voicebox" - Tobacco Free CA

5 years ago • 148,429 views

In this ad from 1996, Debi Austin discusses her struggle to quit smoking even after having her larynx removed due to a tobacco-related cancer diagnosis. The making of the ad prompted...

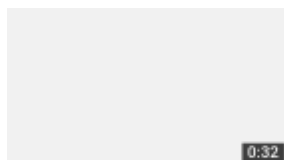


9:28

Debi Austin - Debi's Story - Tobacco Free CA

5 years ago • 80,749 views

Debi Austin started smoking at the age of 13. She continued to smoke through a stoma in her throat even after being diagnosed with cancer and having her larynx removed at the age of ...



0:32

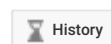
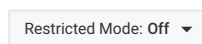
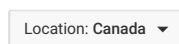
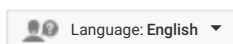
#LostMoments: "Little Fisherman" Ad - Tobacco Free CA

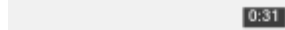
4 years ago • 77,603 views

A sweet moment of a dad showing his boy how to fish. Which moments are you willing to give away since every cigarette shortens your life? Tobacco is still killing 1 in 5 Americans....

Show more

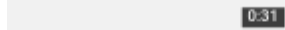
Uploads





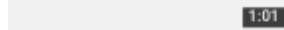
"Lista de Dulces" :30 Radio - Spanish

19 views • 14 hours ago



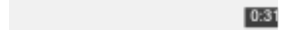
"Candy Shop" :30 Radio

42 views • 14 hours ago



"DJ Mention" :60 Radio - Korean

10 views • 14 hours ago



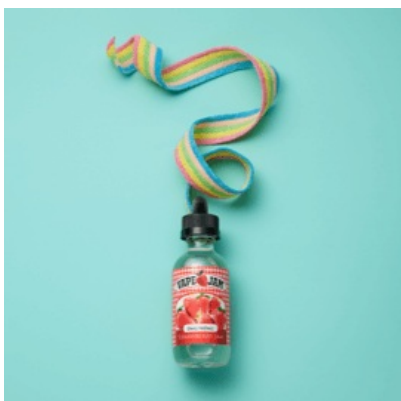
"Blow Their Cover 1" :30 Radio

57 views • 14 hours ago

THIS IS NOT APPLE JUICE.



Why Flavors?



Flavors mask the harsh taste of tobacco, making it easier for kids to get hooked on nicotine. The tobacco companies know this.* They also know that flavor means a whole lot more. It's how we celebrate, how we nurture, and in many cases, how we pass down culture in kitchens all over California.

The emotional ground they're mining is giving way to a terrifying number of flavors, crafting a more-is-more mentality by which kids can always say, *I haven't tried that one. Yet.**

With thousands of flavors, you might wonder how they haven't run out of options. Here's the trick. Not all their flavors are actual flavors. To maximize profit potential, they moved beyond the limits of what kids taste, and into more sacred space of what kids imagine. Cha-ching. Just like that, their product line is boundless. And customized for curiosity.

Sources

Campaign for Tobacco Free Kids, Designed for Addiction Report, 2014 https://www.tobaccofreekids.org/press-releases/2014_06_23_report, "The evidence is now clear: Over the past 50 years, tobacco manufacturers have designed and marketed ever more sophisticated products that are highly effective at creating and sustaining addiction to nicotine, more appealing to new youth smokers and more harmful. They took a deadly and addictive product and made it worse, putting smokers at even greater risk of addiction, disease and death... By altering the taste, smell and other sensory attributes of their products, tobacco manufacturers make it easier for new users – the vast majority of whom are kids – to start and continue smoking"

[View source](#)

Morean ME, Butler ER, Bold KW, Kong G, Camenga DR, Cavallo DA, et al. (2018) "Preferring more e-cigarette flavors is associated with e-cigarette use frequency among adolescents but not adults." PLoS ONE 13(1): e0189015. <https://doi.org/10.1371/journal.pone.0189015> "Despite the limitations, the current study provides preliminary evidence that specific flavor preferences and the use of multiple flavors is associated with more frequent e-cigarette use among youth and that a similar pattern of results was not observed within an adult sample."

[View source](#)

[Do Something](#)

15,500

tobacco flavors and counting

- Razzleberry Ring Pop,
- Candy Corn,
- Cotton Candy,
- Strawberry Shortcake,
- Joosy-Licious,
- Juice Roll Upz,
- Marshmallow Man,
- Pop Clouds,
- Lemon Drops,
- Sour Gummy Worms,
- Double Rainbow,
- It's So Fluffy,
- Bubblegum,
- Brain Freeze,
- Unicorn Poop,
- Coco Pops,
- Lucky Charm,
- Apple Jax,
- Silly Rabbit,
- Choo Choo Crunch,
- Bird Brains,
- Booger Sugar,
- Banana Butt,
- Honey Doo Doo,
- Barney Pebbles,
- Dragon's Blood,
- Dingle Berry,
- Hershey Squirt,
- Vampires Kiss,
- Alien Sight,
- Blueberry Smurf,
- Pegasus Wings,
- Kryptonite,
- French Dude,
- Angry Munchkins,
- Toothfairy Puff,
- Mermaid Tears,

EASIER TO SMOKE, HARDER TO SPOT

Even if they didn't mean to attract kids (history suggests otherwise), that's what they did. You'd think they'd change their tactics to stop more from coming. Instead, they continued to transform their drug into the stuff of childhood, and hook the kids we work so hard to protect.

This is a test

Can you pick out which are tobacco products and which are innocent kid things? Click to play.

Sources

Benham, Barbara, and Stephanie Desmon. "Study: Toxic Metals Found in E-Cigarette Liquids." Johns Hopkins Bloomberg School of Public Health, John Hopkins University, 7 Feb. 2017. www.jhsph.edu/news/news-releases/2017/study-toxic-metals-found-in-e-cigarette-liquids.html.

"The five metals – cadmium, chromium, lead, manganese and nickel – were present in all five brands, with cadmium markedly lower than the other metals and with a considerable range of concentrations among the brands. For instance, one brand had a high

concentration of all five metals. In that brand, the concentration of nickel, which is considered the most serious carcinogen when inhaled, was 22,600 micrograms per liter, 400 times that of the brand with the lowest concentration of nickel. In that same brand, the one with the highest concentration of all five metals, the concentration of manganese was 690 micrograms per liter, or 240 times that of the lowest concentration in yet another brand.”

[View source](#)

“There are > 7,000 e-cigarette flavors currently marketed. Flavoring chemicals gained notoriety in the early 2000s when inhalation exposure of the flavoring chemical diacetyl was found to be associated with a disease that became known as “popcorn lung.” There has been limited research on flavoring chemicals in e-cigarettes.”

Allen, Joseph, et al. “Flavoring Chemicals in E-Cigarettes: Diacetyl, 2,3-Pentanedione, and Acetoin in a Sample of 51 Products, Including Fruit-, Candy-, and Cocktail-Flavored E-Cigarettes.” Environmental Health Perspectives, U.S. Department of Health and Human Services, ehp.niehs.nih.gov/15-10185/.
<https://ehp.niehs.nih.gov/15-10185/>

“Diacetyl—a flavoring compound associated with the development of “popcorn lung” in workers after inhalation exposure—was detected in 39 of the 51 flavored e-cigarettes tested in this study, including flavors that have particular appeal to children, teenagers, and young adults. Forty-seven of the 51 flavors tested in our study had at least one of the three flavoring compounds detected.”

[View source](#)

“JUULPods & Juice.” JUUL, support.juulvapor.com/home/learn/faqs/juulpods-juice.
<https://support.juulvapor.com/home/learn/faqs/juulpods-juice>

“Each JUULpod contains 0.7mL with 5% nicotine by weight at time of manufacture which is approximately equivalent to 1 pack of cigarettes or 200 puffs. Nicotine content may decrease over an extended period of time.”

[View source](#)

The highly toxic liquid in e-cigarettes is responsible for a surge of child poisonings; just one teaspoon may be enough to kill your child

<https://articles.mercola.com/sites/articles/archive/2014/05/28/e-cigarette-poisoning.aspx>

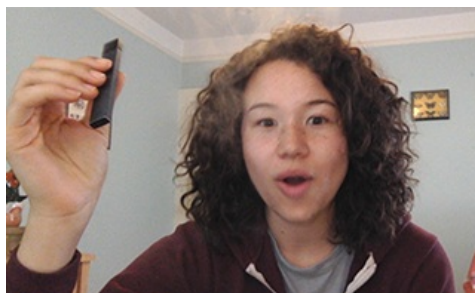
https://www.nytimes.com/2014/03/24/business/selling-a-poison-by-the-barrel-liquid-nicotine-for-e-cigarettes.html?_r=0

[View source](#)

The committee found conclusive evidence that drinking or injecting e-liquids can be fatal, that exposure to the skin or eyes can cause seizures and other serious problems, and that e-cigarette devices can explode and cause burns and other injuries.
<https://www.nytimes.com/2018/01/23/health/e-cigarettes-health-evidence.html>

[View source](#)

While you were learning about your kids’ favorite flavor ☐ The Tobacco Industry was, too.





KNOW THE SIGNS

How are kids getting it?

While California State Law prohibits the sale of tobacco products to anyone under 21, kids get it. Here are seven common ways:

- Vape products are all over social media, and many promote the sale of their products right from their accounts.
- Website age gates are easily bypassed, and kids use a parent's name for shipping. In fact, Kids successfully buy e-cigs online 94% of the time.*
- Clerks at tobacco shops, vape stores, gas station and convenience store might not enforce the law not to sell to anyone under 21 years old.
- Many vape companies have names that wouldn't raise a red flag on parents' credit card statements.
- Online orders can be delivered to Amazon lockers in supermarkets or convenience stores.
- Orders can also be shipped to the homes where parent(s) are at work when the mail comes.
- Twenty somethings can make the purchase legally, and can give or sell tobacco products to younger kids.

How to tell if your kid is vaping?

- If their room smells artificially sweet, don't assume it's a scented candle.*
- Nosebleeds are common among Juul users.*
- Many vapors report increased thirst.*
- There is often a heightened caffeine sensitivity.*

Sources

"One patient, a student at a prestigious local private school, secretly used his parents' credit cards to buy thousands of dollars of Juuls online, and then turned around and sold the devices and flavored pods to other kids at a profit."

<https://www.bostonglobe.com/metro/2017/11/15/where-teenagers-are-high-school-bathrooms-vaping/lJ6xYWWlOTKqsUGTTlw4UO/story.html> The same doctor talks about prepaid debit cards here:
<https://www.fox25boston.com/news/local-doctor-warns-parents-of-dangers-of-juul-e-cigarettes/548847718>

[View source](#)

At Pali, this black market is far-reaching and prosperous. Sophomore Jackson* says, "Buying and selling pods at Pali is huge. I see it every day." <https://www.tidelinenews.com/single-post/2017/09/22/Juul-Never-Believe-It-The-Rise-of-Teen-Vaping>

[View source](#)

The complaints from the public filed with the FDA cited trouble breathing, headache, cough, dizziness, sore throat, nose bleeds, chest pain or other cardiovascular problems, and allergic reactions such as itchiness and swelling of the lips.

https://www.huffingtonpost.com/2014/04/17/more-ecigarette-injuries_n_5165480.html

[View source](#)

One major ingredient in the vaporized liquid in e-cigs is propylene glycol, which is "hygroscopic" -- meaning it attracts and holds water molecules from its environment, like the mouth. According to Genovese, this can lead e-cig users to have a constant state of dry mouth, which can be alleviated by quaffing more drinks. Dry skin is another common side effect.

https://thestir.cafemom.com/tweens_teens/181206/signs_kid_using_vaping_ecigarettes

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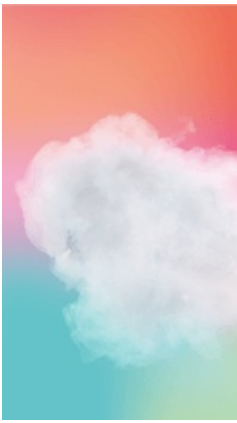
Passing on caffeine. Some e-cig users develop a sensitivity to caffeine, and curb their caffeine intake. So if your teen is suddenly passing on the Red Bulls they used to chug often, vaping may be to blame.

https://thestir.cafemom.com/tweens_teens/181206/signs_kid_using_vaping_ecigarettes

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Williams, Rebecca S., et al. "Electronic Cigarette Sales to Minors via the Internet." JAMA Pediatrics, American Medical Association, 2 Mar. 2015, jamanetwork.com/journals/jamapediatrics/fullarticle/2174572.

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4 of 5

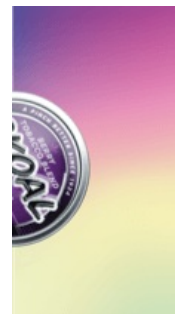
Kids who have used tobacco started with a flavored product.*

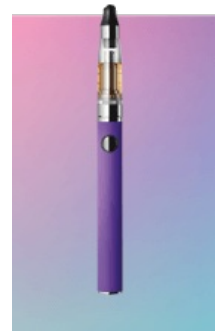
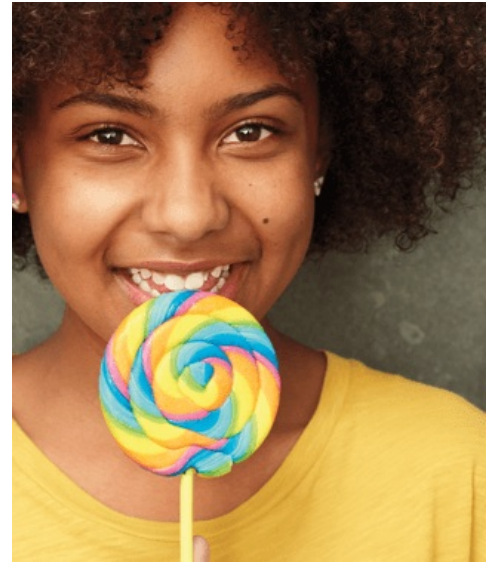
The brain's peak period for developing
addiction starts in adolescence.*

Early exposure to nicotine paves
a pathway for addiction of all kinds.*



The less dangerous tobacco seems to teens,
the more they use it.*





Sources

<https://www.tobaccofreekids.org/assets/factsheets/0383.pdf>

Pg 3. - "Research shows that flavored products – no matter what the tobacco product – appeal to youth and young adults. Data from the 2013-2014 Population Assessment of Tobacco and Health (PATH) study found that 80.8 percent of 12-17 year olds who had ever used a tobacco product initiated tobacco use with a flavored product..."

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<https://www.ncbi.nlm.nih.gov/pubmed/28318902>

Am J Prev Med. 2017 Aug;53(2):139-151. doi: 10.1016/j.amepre.2017.01.026. Epub 2017 Mar 16. Flavored Tobacco Product Use in Youth and Adults: Findings From the First Wave of the PATH Study (2013-2014). . "Eighty-one percent of youth and 86% of young adult ever tobacco users reported that their first product was flavored..."

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Song, A.V., H.E. Morrell, J.L. Cornell, et al., "Perceptions of Smoking-Related Risks and Benefits as Predictors of Adolescent Smoking Initiation," American Journal of Public Health, 99(3):487-492, 2009.

[4] Huang, L.-L., H.M. Baker, C. Meernik, et al., "Impact of Non-menthol Flavours in Tobacco Products on Perceptions and Use Among Youth, Young Adults and Adults: A Systematic Review," Tobacco Control, 26(6):709-719, 2017.

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Song, A.V., H.E. Morrell, J.L. Cornell, et al., "Perceptions of Smoking-Related Risks and Benefits as Predictors of Adolescent Smoking Initiation," American Journal of Public Health, 99(3):487-492, 2009.

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Kowitt, S.D., C. Meernik, H.M. Baker, et al., "Perceptions and Experiences With Flavored Non-Menthol Tobacco Products: A Systematic Review of Qualitative Studies," International Journal of Environmental Research and Public Health, 14(4):338, 2017.

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<https://www.tobaccofreekids.org/assets/factsheets/0383.pdf>

Pg 3. - "Research shows that flavored products – no matter what the tobacco product – appeal to youth and young adults. Data from the 2013-2014 Population Assessment of Tobacco and Health (PATH) study found that 80.8 percent of 12-17 year olds who had ever used a tobacco product initiated tobacco use with a flavored product..."

* Here is the published PATH study: <https://www.ncbi.nlm.nih.gov/pubmed/28318902>

Am J Prev Med. 2017 Aug;53(2):139-151. doi: 10.1016/j.amepre.2017.01.026. Epub 2017 Mar 16. Flavored Tobacco Product Use in Youth and Adults: Findings From the First Wave of the PATH Study (2013-2014). . "Eighty-one percent of youth and 86% of young adult ever tobacco users reported that their first product was flavored..."

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<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3543069/>

[View source](#)

<https://e-cigarettes.surgeongeneral.gov/knowtherisks.html>; * <https://www.ncbi.nlm.nih.gov/books/NBK99242/> SGReport, Preventing Tobacco Use Among Youth and Young Adults

Evidence also shows that smoking can be a first step toward other substance abuse. Stopping or delaying that first step will reduce the risk that kids will progress to using other harmful substances.

<https://www.tobaccofreekids.org/assets/factsheets/0127.pdf>

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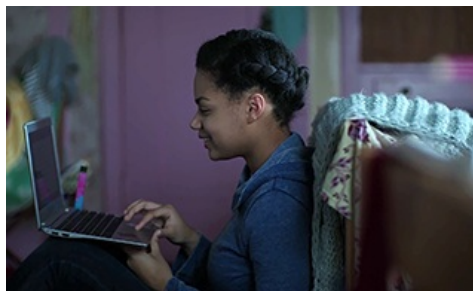
Elfenbein, Eddy. "The Stunning Success of Tobacco Investing." Crossing Wall Street RSS, 24 Apr. 2017, www.crossingwallstreet.com/archives/2017/04/the-stunning-success-of-tobacco-investing.html.

"The S&P 500 Tobacco Index fell 22% between 1998 and 2002. Over the past decade, it's up 178%, outperforming the broader S&P 500, which climbed 58%."

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Why Kids?

Don't miss the tobacco industry's latest scam.



Health Facts

Cigarillos have

3

x

the tobacco of cigarettes, and can lead to lung and oral cancers, plus heart disease, chronic obstructive pulmonary disease, and aortic aneurysms.*

Tobacco use kills more Americans than AIDS, alcohol, motor vehicles, homicide, illegal drugs and suicide

COMBINED*

E-juice causes arterial stiffness, associated with an increased risk of

heart attacks and strokes

in later life.*

Do Something

Sources

"Cigar Smoking and Cancer." National Cancer Institute, National Institutes of Health, www.cancer.gov/about-cancer/causes-prevention/risk/tobacco/cigars-fact-sheet. =

"Cigarettes are uniform in size and contain less than 1 gram of tobacco each. Cigarillos are a type of smaller cigar. They are a little bigger than little cigars and cigarettes and contain about 3 grams of tobacco."

View source

Chang, Cindy M, et al. "Systematic Review of Cigar Smoking and All Cause and Smoking Related Mortality." BMC Public Health, BioMed Central, 24 Apr. 2015, www.ncbi.nlm.nih.gov/pmc/articles/PMC4408600/.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4408600/>

"Primary cigar smoking (current, exclusive cigar smoking with no history of previous cigarette or pipe smoking) was associated with all cause-mortality, oral cancer, esophageal cancer, pancreatic cancer, laryngeal cancer, lung cancer, coronary heart disease (CHD), and aortic aneurysm."

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"The Toll of Tobacco in the United States." Campaign for Tobacco-Free Kids, Campaign for Tobacco-Free Kids, 10 Apr. 2018, www.tobaccofreekids.org/problem/toll-us.

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European Lung Foundation. "E-cigarettes linked to increased arterial stiffness, blood pressure and heart rate in humans." ScienceDaily. ScienceDaily, 10 September 2017. .

In the first 30 minutes after smoking e-cigarettes containing nicotine, there was a significant increase in blood pressure, heart rate and arterial stiffness; no such effect was seen on heart rate and arterial stiffness in the volunteers who had smoked e-cigarettes without nicotine.

The immediate increase in arterial stiffness that we saw is most likely attributed to nicotine," said Dr Lundbäck. "The increase was temporary. However, the same temporary effects on arterial stiffness have also been demonstrated following use of conventional cigarettes. Chronic exposure to both active and passive cigarette smoking causes a permanent increase in arterial stiffness. Therefore, we speculate that chronic exposure to e-cigarettes with nicotine may cause permanent effects on arterial stiffness in the long term.

View source

BRAIN SCIENCE FOR REGULAR PEOPLE

To explain why the tobacco industry targets kids, we have to lay down a little science.

1. 1

Nicotine changes the brain, which is why quitting is so hard.*

2. 2

The tobacco industry profits off addiction.

3. 3

The brain's peak period to develop addiction is in adolescence.*

4. 4

If you think it's coincidence that kids are the likeliest addicts and that tobacco now tastes like candy, go back to number two.

Sources

When you smoke, the nicotine actually changes the brain – that's why quitting is so hard.

https://www.tobaccofreekids.org/assets/content/what_we_do/industry_watch/doj/corrective_statements/2017_10_corrective_statements.pdf

View source

Comparing smoking behavior of adolescents to that of adults may point to an enhanced sensitivity of the adolescent brain to addictive properties of nicotine. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3543069/>

[View source](#)

Do something

SEND A LETTER OF CONCERN TO YOUR MAYOR:

Dear Mayor

My name is and I am a resident of .

I am writing because I am concerned about the tobacco industry's use of flavors in their toxic products to lure kids into lifelong addiction. The tobacco industry doesn't stop at the use of flavors, it also uses kid-friendly packaging to deceive kids into thinking their products are harmless. This, coupled with unchecked online purchasing, gets tobacco products past parents and teachers and straight into the hands of kids. All of this is a recipe for disaster.

The tobacco industry's use of flavors is very strategic, as it targets the age group most susceptible to addiction. The youth in our area face enough challenges in this time of their development. We should be setting them up for success, not saddling them with addiction that could torment them all their lives. They deserve better.

I ask for your leadership in addressing how we can keep our kids safe from an industry determined to do them harm.

Sincerely,

[Send My Letter](#)



INTERESTED IN JOINING A LOCAL TOBACCO CONTROL COALITION?

Sign up to find out how you can help stop the tobacco industry from targeting our children.

[Send me more information](#)

SHARE WILDLY

The tobacco industry's success hinges on their ability to deceive us. Get this in front of as many eyes as you can. We can't stop it if we don't see it.

Choose what image you want to share:

☐





ADDITIONAL RESOURCES

- US Surgeon General, Know the Risks: E-cigarettes & Young People

Get tips on how the talk with your teen can be a successful experience for both of you.

[Visit Resource](#)

- Campaign for Tobacco-Free Kids, The Flavor Trap

Get a handle on the tobacco industry's tactics, both current and past, to hook kids for life.

[Visit Resource](#)

- New York Times, The Juul is Too Cool

Learn about the cultural impact of the Juul e-cig from this kid-focused on-the-ground reporting.

[Visit Resource](#)

Statement from FDA Commissioner Scott Gottlieb, M.D., on new enforcement actions and a Youth Tobacco Prevention Plan to stop youth use of, and access to, JUUL and other e-cigarettes

 [fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm605432.htm](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm605432.htm)

- **FDA cites 40 retailers for violations related to youth sales of JUUL e-cigarettes**
- **Agency announces a new blitz of retail establishments targeting youth sale violations**
- **Agency takes new action to examine youth appeal of JUUL**
- **Agency takes steps to foreclose online sales of JUUL to minors**
- **These are the first steps in a new effort aimed at stopping youth use of e-cigarettes**

Protecting our nation's youth from the dangers of tobacco products is among the most important responsibilities of the U.S. Food and Drug Administration – and it's an obligation I take personally. We recognize that if the FDA is to end the tragic cycle of successive generations of nicotine and tobacco addiction, we must take every opportunity to disrupt that process where it starts: youth access to and use of tobacco products.

That's why, as part of our [comprehensive plan](#) announced in July, we're pursuing a policy to prevent future generations from becoming addicted in the first place by rendering cigarettes minimally or non-addictive. A key part of that plan was establishing the foundational framework for regulating non-combustible tobacco products for adults, like e-cigarettes.

But as we work to keep kids from making the deadly progression from experimentation to regular cigarette use, it's imperative that we also make sure children and teenagers aren't getting hooked on more novel nicotine-delivery products.

Today, we're announcing several new actions and efforts aimed at doing just that as the first steps in a new Youth Tobacco Prevention Plan focused on stopping youth use of tobacco products, and in particular, e-cigarettes.

The troubling reality is that electronic nicotine delivery systems (ENDS) such as e-cigarettes have become wildly popular with kids. We understand, by all accounts, many of them may be using products that closely resemble a USB flash drive, have high levels of nicotine and emissions that are hard to see. These characteristics may facilitate youth use, by making the products more attractive to children and teens.

These products are also more difficult for parents and teachers to recognize or detect. Several of these products fall under the JUUL brand, but other brands, such as myblu and KandyPens, that have similar characteristics are emerging. In some cases, our kids are trying these products and liking them without even knowing they contain nicotine. And that's a problem, because as we know the nicotine in these products can rewire an

adolescent's brain, leading to years of addiction. For this reason, the FDA must – and will – move quickly to reverse these disturbing trends, and, in particular, address the surging youth uptake of JUUL and other products.

To address all of these concerns, the FDA is announcing a series of new enforcement and regulatory steps.

First, we're announcing that the FDA has been conducting a large-scale, undercover nationwide blitz to crack down on the sale of e-cigarettes – specifically JUUL products – to minors at both brick-and-mortar and online retailers. The blitz, which started April 6 and will continue to the end of the month, has already revealed numerous violations of the law.

The illegal sale of these JUUL products to minors is concerning. In fact, just since the beginning of March, FDA compliance checks have uncovered 40 violations for illegal sales of JUUL products to youth. The FDA has issued 40 warning letters for those violations, which we are also announcing today. This includes warning letters that are the result of the blitz. Others are a result of our sustained enforcement efforts to reduce tobacco product sales to minors. And we anticipate taking many more similar actions as a result of the ongoing blitz and our focus on enforcement related to youth access.

We'll hold retailers accountable for continued violations. Let me be clear to retailers. This blitz, and resulting actions, should serve as notice that we will not tolerate the sale of any tobacco products to youth.

This isn't the first time we've taken action against retailers for selling these e-cigarettes and other tobacco products to minors, and it won't be the last. In fact, the FDA has conducted 908,280 inspections of retail establishments that sell tobacco products, issued 70,350 warning letters to retailers for violating the law and initiated about 17,000 civil money penalty cases. We have also issued more than 110 No-Tobacco-Sale Order Complaints, which can result in retailers being prohibited from even selling tobacco products for specified periods of time.

It's clear there's need for strong federal enforcement of these important youth access restrictions and we'll continue to hold retailers accountable by vigorously enforcing the law with the help of our state partners. Today's action should serve to put retailers on notice to stop selling products to minors.

Second, as part of this effort, we also recently contacted eBay to raise concerns over several listings for JUUL products on its website. We're thankful for eBay's swift action to remove the listings and voluntarily implement new measures to prevent new listings from being posted to the web retailer's site. Our overarching goal – one we hope everyone shares – is to make sure JUUL, and any other e-cigarettes or tobacco products, aren't getting into kids' hands in the first place.

Third, we're also taking additional steps to contact the manufacturers directly, and hold them accountable. We need to examine all the available information to understand why kids are finding these products so appealing – and address it.

That's why today, the FDA also sent an official request for information directly to JUUL Labs, requiring the company to submit important documents to better understand the reportedly high rates of youth use and the particular youth appeal of these products. The information we're requesting includes: documents related to product marketing; research on the health, toxicological, behavioral or physiologic effects of the products, including youth initiation and use; whether certain product design features, ingredients or specifications appeal to different age groups; and youth-related adverse events and consumer complaints associated with the products. We don't yet fully understand why these products are so popular among youth. But it's imperative that we figure it out, and fast. These documents may help us get there.

We plan to issue additional letters to other manufacturers of products that raise similar concerns about youth use. If these companies, including JUUL, don't comply with our requests, they will be in violation of the law and subject to enforcement.

Fourth, we are planning additional enforcement actions focused on companies that we think are marketing products in ways that are misleading to kids. I will have more to say on this in the coming weeks.

These actions are just the first in a series of efforts we're pursuing as part of our newly formed Youth Tobacco Prevention Plan. We will announce additional steps in the coming weeks and months. And I hope that this sends a clear message to all tobacco product manufacturers and retailers that the FDA is taking on this issue with urgency, and if kids are flocking to your product or you're illegally selling these products to kids, you're on the agency's radar.

We appreciate that JUUL Labs has already expressed recognition of this problem and has reached out to the FDA and other stakeholders to discuss these concerns. But we must all recognize that more needs to be done. As we've said before, there is no acceptable number of children using tobacco products. We share the belief that these products should never be marketed to, sold to, or used by kids – and we need to make every effort to prevent kids from getting hooked on nicotine. This responsibility falls not only to the FDA, but also the companies making these products, the retailers selling them, and the online venues that help to fuel the teen popularity of, and access to, these products.

Finally, as we pursue additional steps to keep kids from using tobacco products, we're also continuing to invest in our compelling, science-based campaigns to educate youth about the dangers of all tobacco products including e-cigarettes.

Last fall, the first content from our youth e-cigarette prevention campaign – an ad showing youth using a USB-like tobacco product – launched online. A full-scale e-cigarette prevention effort under "The Real Cost" brand umbrella is planned for a September launch.

We're also exploring clear and meaningful measures to make tobacco products less toxic, appealing and addictive with an intense focus on youth. Specifically, as part of our comprehensive plan, we intend to pursue product standards and other regulations for electronic nicotine delivery systems, such as e-cigarettes, to address known hazards and concerns, including exploding batteries and accidental ingestion. Ultimately, our work on tobacco and nicotine regulation is aimed at achieving the greatest public health benefit.

Make no mistake. We see the possibility for ENDS products like e-cigarettes and other novel forms of nicotine-delivery to provide a potentially less harmful alternative for currently addicted individual adult smokers who still want to get access to satisfying levels of nicotine without many of the harmful effects that come with the combustion of tobacco. But we've got to step in to protect our kids.

As the FDA considers regulating nicotine levels in cigarettes to render combustible cigarettes minimally or non-addictive, products such as e-cigarettes may offer a potentially lower risk alternative for individual adult smokers. These ENDS products will still need to be put through an appropriate series of regulatory gates by the FDA. But the viability of these products is severely undermined if those products entice youth to start using tobacco and nicotine.

The youth-focused steps we're taking are consistent with our responsibility to protect kids and significantly reduce tobacco-related disease and death, and I intend to do everything within my power to fulfill that duty.

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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April 24, 2018

Submission Tracking Number (STN): RD0000476

JUUL Labs, Inc.
660 Alabama Street
2nd Floor
San Francisco, CA 94110

Dear Mr. Ziad Rouag:

Under Section 904(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is requesting that JUUL Labs, Inc. (JUUL) submit documents relating to marketing practices and research on marketing, effects of product design, public health impact, and adverse experiences and complaints related to JUUL products. This request applies to research relating to all such tobacco products and their components or parts, including those products for research, investigational use, developmental studies, test marketing, and/or commercial marketing.

FDA is requesting these documents based on growing concern about the popularity of JUUL products among youth. JUUL product use appears to be common in middle and high schools based on widespread media reporting describing a rapid growth of use among youth in general and on school property,¹ numerous complaints that have been received by CTP, small research studies that have

¹ *NY Times*, April, 2018: <https://www.nytimes.com/2018/04/02/health/vaping-ecigarettes-addiction-teen.html>; *Vogue*, April 2, 2018: <https://www.vogue.com/article/vaping-health-risks-e-cigarettes-teenagers-addiction-toxic-metal-heat-lungs-heart-attack-juul>; *Chicago Tribune*, February 2018: <http://www.chicagotribune.com/news/ct-met-juul-ecigarettes-at-schools-20180209-story.html>; *Buzzfeed*, February 2018: https://www.buzzfeed.com/carolinekee/juul-ecigarette-vape-health-effects?utm_term=.thP0N67x7p#.pkN2Ee0q0l; *Business Insider*, March 2018: <http://www.businessinsider.com/juul-e-cig-vaping-health-effects-2018-3>; *Sioux Falls (SD) Argus Leader*, April 2018: <https://www.argusleader.com/story/news/2018/04/17/concerns-grow-more-kids-caught-vaping-juuling-s-d-schools/523447002/>; North New Jersey, January 2018: <https://www.northjersey.com/story/news/passaic/wanaque/2018/01/16/students-vaping-epidemic-schools/1006178001/>; *US News*, March 2018: <https://health.usnews.com/wellness/health-buzz/articles/2018-03-15/kids-are-trying-juul-e-cigarettes-and-experts-are-concerned>; *Pittsburgh Post-Gazette*, December 2017: <http://www.post-gazette.com/local/region/2017/12/12/JUUL-vaporizer-nicotine-flash-drive-small-concealable-e-cigarette/stories/201712120151>; *MSN*, April 2018: <https://www.msn.com/en-us/health/watch/%E2%80%98juuling%E2%80%99-is-%E2%80%98not-safe%E2%80%99-medical-expert-warns-on-megyn-kelly-today/vp-AAvnnc1>; *NPR*, December 2017: <https://www.npr.org/sections/health-shots/2017/12/04/568273801/teenagers-embrace-juul-saying-its-discreet-enough-to-vape-in-class>

raised concerns,^{2,3} and social media evidence of youth use.^{4,5} Widespread reports of youth use of JUUL products are of great public health concern and no child or teenager should ever use any tobacco product. Nicotine affects the developing brain⁶ and youth may not understand the nicotine or other characteristics of JUUL.^{3,7} JUUL products may have features that make them more appealing to kids and easier to use, thus causing increased initiation and/or use among youth. Similar to other electronic nicotine delivery system (ENDS) products, JUUL product use during adolescence may lead to cigarette smoking or use of other tobacco products in the future.⁸ Their appeal may be related to different aspects of the product, including the product design, promotion, or distribution, and CTP seeks information to further understand the appeal and use.

I. Submission Content

A. Submission of Documents Pursuant to a Section 904(b) Request

In accordance with section 904(b) of the FD&C Act, FDA requests that you submit all documents (including underlying scientific and financial information, as specified below) relating to marketing practices and research activities and research findings, conducted, supported, or possessed by you or your agents relating to a specified set of topics, as set forth below. The request includes but is not limited to documents relating to research findings and activities, if any, that you possess as the result of acquiring or merging with, or obtaining the services or products of another company. For purposes of this request, “research” may include, but is not limited to focus groups, surveys, experimental clinical studies, toxicological and biochemical assays, *in vivo* and *in vitro* assays including animal testing, laboratory formulation and processing testing, taste panels, and assessments of the effectiveness of product marketing practices. The request applies to research relating to any and all ENDS products including the components or parts of such products, including but not limited to products for research, investigational use, developmental studies, test marketing, and/or commercial marketing.

For products not manufactured in the United States, the request applies to the extent you have imported such products into the United States. An importer of a tobacco product not manufactured in the United States is required to supply the information required of the manufacturer of that product.

² Jackson A, Kong G, Camenga D et al. (March 2018). *High School Adolescents Use Several Types of E-cigarette Devices*. Poster session presented at Society for Research on Nicotine and Tobacco, Baltimore, MD.

³ Willlet JG, Bennett M, Hair, EC, et al. *Recognition, use and perceptions of JUUL among youth and young adults*. Tobacco Control. Epub ahead of print: April 17, 2018. doi: 10.1136/tobaccocontrol-2018-054273.

⁴ Kavuluru R, Han S, Hahn EJ. *On the popularity of the USB flash drive-shaped electronic cigarette Juul*. Tobacco Control Epub ahead of print: April 17, 2018. doi:10.1136/tobaccocontrol-2018-054259.

⁵ Brett E, Hebert E, Stevens E, et al. (March 2018). *An Analysis of JUUL discussions on social Media: Using Reddit to understand patterns of use and perceptions of JUUL*. Poster session presented at Society for Research on Nicotine and Tobacco, Baltimore, MD.

⁶ U.S. Department of Health and Human Services. *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention.

⁷ <https://www.marketwatch.com/story/many-young-people-are-missing-something-important-about-popular-e-cigarette-juul-2018-04-18>

⁸ National Academies of Science, Engineering, and Medicine. 2018. *Public Health Consequences of E-cigarettes*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/24952>.

1. Topics

Pursuant to section 904(b), FDA requests all documents (including underlying scientific and financial information, as specified below) relating to research activities and findings (including marketing research) and marketing practices, developed for JUUL subject to the limitations in I.A.2 of this letter, on *all* of the following topics:

1. Product marketing— documents (including underlying scientific or financial information) related to marketing research or marketing practices and the effectiveness of such practices. Potential relevant areas of research or marketing practices include:
 - Target consumer groups, including direct (e.g., smokers, ENDS users) and indirect (e.g., youth)
 - Consumer perception studies/market testing
 - Marketing themes and content, including depictions of young people and how ENDS are characterized
 - Means of advertisement and promotion, such as:
 - General marketing strategies (e.g., social media)
 - Price promotions, promotional games and contests
 - Retailer agreements/incentives or partnerships with media and publishing organizations
 - Any other consumer or business-to-business advertising or promotion strategies not listed above
 - Educational materials or products for schools to limit youth use
 - Means of product distribution as it might relate to youth exposure to marketing or youth access to JUUL products
 - Information about how youth are accessing JUUL and information about how the company plans to prevent youth from gaining access to JUUL
2. Product design— documents (including underlying scientific information) related to research on the health, toxicological, behavioral, and physiologic effects, including appeal or addictive potential for youth, as it relates to product design, including the following:
 - Product shape or form (e.g., similarity in appearance to USB stick)
 - Nicotine formulation, (e.g., nicotine salt formula) and nicotine concentration/content
 - Flavors
 - Product features such as: appearance, or lack thereof, of plume; safety features/prevention of misuse; USB port rechargeability
3. Public health impacts involving youth—documents (including underlying scientific information, such as survey information) related to research on the health, toxicological, behavioral, or physiologic effects of JUUL products on youth, including, but not limited to:
 - Awareness, susceptibility, intentions to use, and use patterns (e.g., frequency of use, dual use with other tobacco products; pharmacokinetics and topography)
 - Perceptions of risk, harm, and addictiveness compared to other ENDS products, other tobacco products, and in general
 - Appeal, liking, product satisfaction

- Health impacts of short-term and long-term use
- 4. Adverse experiences and complaints involving youth—documents (including underlying scientific information) related to research on health, toxicological, behavioral, or physiologic effects described in adverse experience reports or consumer complaints related to youth use associated with JUUL products, including:
 - Reports of youth use and uptake
 - Reports of addiction or withdrawal
 - Reports of acute hazards or risk of injury

2. Limitations — types of documents and information

With respect to the topics listed above, FDA requests *all* of the following documents and information:

- Study proposals, original implemented protocols (including all amendments), analysis plans, agreements, notebooks, data collection tools, including, but not limited to, forms and assessment scales for planned, ongoing, or completed studies, surveys, and other research, whether for external release or internal use
- Final data analyses and reports regarding studies, surveys, data compilations, or other research, whether for external or internal use (if there were no final analyses, interim data analyses should be submitted)
- Posters and/or presentations exhibited or to be exhibited at external meetings or conferences if the underlying data has not been presented in other documents and information within this request
- Manuscripts, articles, editorials, and letters that have been submitted for publication but not yet published (e.g., in review, accepted, rejected)
- Underlying data (e.g., in the form of spreadsheets, datasets, charts, tables, and diagrams) analyzed to produce any of the data analyses, reports, posters, manuscripts, or articles requested above

With respect to documents, FDA requests only the final version, or in the absence of a final version, the most recent draft of each document. Please do not submit (a) past iterations of a completed or more recent document, (b) document duplicates, or (c) near duplicates that only vary in minor ways (e.g., differences in addressee or changes in letterhead). FDA does not request published (publicly available) press releases, abstracts, editorials, letters, manuscripts, material safety data sheets (MSDS), and HHS correspondences; if you seek to voluntarily submit such information, we request a list of such publications be provided as a separate appendix only, in lieu of submitting such publications. Electronic mail should be in portable document format (.pdf) and responsive to the above topic areas. Transmittal email should not be included. Submitted documents should not be redacted.

Included within the request are supporting summary reports and the underlying data that support those reports. FDA asks that spreadsheets or datasets be submitted both in pdf and in a file type and structured format that allows for meaningful review and analysis of the data (e.g., Excel (.xls), comma separated values (.csv), or SAS transport (.xpt). Where relevant, data submissions should be accompanied by the name and version of software used to create the file, names and definitions of variables, and copies of programs and macros needed to generate

your analyses. Your submission should include any data analyses that stratify scientific results by one or more of the following: gender, race/ethnicity, age, health condition, or other similar factors.

As an option, information responsive to this 904(b) request that has been previously provided to FDA under section 904 the FD&C Act does not have to be re-submitted as long as the document is fully referenced in the metadata load file.

3. Date for submission of documents

All information for this request is to be received by FDA no later than June 19, 2018. **If you do not have any documents responsive to this request, inform FDA of this in writing by June 19, 2018.** If you anticipate difficulties with this document production, please contact FDA within 30 days of this letter so that we may assist you in resolving any technical difficulties you may have and facilitate compliance with the above time line.

Failure to provide information requested by FDA in accordance with section 904(b) of the FD&C Act is a violation of the FD&C Act and subject to regulatory and enforcement action by FDA.

B. Submission of Additional Information

To provide context and background for the 904(b) requests in section I.A of this letter, FDA also asks that you voluntarily submit a summary (one to five pages in length) for each of the topics in section I.A that includes the number and type of documents included, and a high-level overview of the content

II. Submission Instructions

Consistent with applicable statutes and regulations, the confidentiality of trade secret and confidential commercial information submitted to FDA pursuant to this request will be preserved.

Please see the enclosed document for guidance in preparing your submission to FDA.

Clearly identify the manufacturer's or importer's name and address, include the label "**FDA 04-2018 JUUL Request for RD0000476**", and submitted electronically via the CTP Portal⁹ using eSubmitter¹⁰.

9

<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm>. FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

¹⁰ <http://www.fda.gov/ForIndustry/FDAeSubmitter>

Alternatively, CD-ROM, DVD, or hard drive submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and FDA Electronic Submission Gateway (ESG) are both generally available 24 hours a day, seven days a week. Submissions delivered to DCC by couriers or physical mail will be considered timely if received during delivery hours on or before the due date¹¹; if the due date falls on a weekend or holiday the delivery must be received on the prior business day. We are unable to accept regulatory submissions by e-mail.

If you have questions regarding this document request, please contact Jaime Golwalla, Regulatory Health Project Manager, at 301-796-2878.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2018.04.24 08:15:33 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

Enclosure

¹¹ <http://www.fda.gov/TobaccoProducts/AboutCTP/ContactUs/default.htm>

Enclosure: Submission Information

A. General Instructions

We request that you submit documents and related material on a CD-ROM, DVD, or hard drive. Documents should be in text-searchable PDF file(s) per FDA guidance on electronic submissions, the FDA eSubmitter User Manual, and the National Archives and Records Administration (NARA) Technical Guidelines for Digitizing Archival Materials for Electronic Access, for document preservation of content and format. The files should include a signed cover letter prominently identified as “**FDA 04-2018 JUUL Request for RD0000476,**” and should also identify the software (name, version, and company) that you used to confirm the submission is free of viruses or other malware. The cover letter should include the number of documents you are submitting for each of the topics. The electronic media should be labeled with your company name, a contact phone number, “FDA 04-2018 JUUL Request for RD0000476,” submission date, and series number (e.g., “disc 1 of 2”).

In order for FDA to accept, access, review, and archive the documents, all documents are to be submitted in their native color and files, including compressed files and archives, cannot be password protected. File formats that should be avoided are proprietary, requiring specialized software to read, and active content that can contain macros or change the content upon opening the file. Ensure all documents are text-searchable and restriction settings under Document Properties are set to “allowed”. If you submit PDF files, they should not contain any attached, embedded, or bundled files. If any documents are scanned, you should verify the accuracy of optical character recognition and legibility of the document. In addition, multi-page documents should be properly unitized, instead of several single-page files.

B. Instructions for Information Submitted Under Section I.A

To ensure accessibility of your documents and facilitate more fluent and efficient communication between you and FDA regarding your submissions, FDA recommends that you take the following steps:

- Uniquely number all pages of your submission, a process commonly referred to in the litigation context as Bates numbering
- Translate all foreign language documents into English
- Create and submit a glossary or explanation of any abbreviations, jargon, or internal names (e.g., code names)

To provide context and background for each document, FDA recommends inclusion of a load file containing the following metadata for each document:

- Manufacturer filing the document
- Filename
- Document date
- Document author(s)
- Document recipient(s)
- Document custodian
- Document title or identification number
- Beginning and ending Bates numbers
- Bates number ranges for other documents physically or digitally attached to the document

- OCR text (for scanned paper documents)
- Identification of each document as one of the following document types: Email, Briefing Slides, Publication, Memo, Report, Meeting minutes, Proposal, Study design, Other;
- Topic(s) (i.e., the topic or topics listed in Section I.A.1 of the attached letter to which the document relates)
- Product name(s) (e.g., brand or sub-brand, or a unique, consistent identifying name for any tobacco product in research or development)
- Product identification number
- Identify the presence of each document in the University of California San Francisco Truth Tobacco Industry Documents Library¹² (formerly Legacy Tobacco Documents Library) as one of the following: present with the Bates number (begin Bates number to end Bates number), not present, or unknown
- For information previously provided to FDA:
 - Date of previous FDA submission
 - Regulatory section under which the document was submitted
 - File name
 - File extension
 - Bates number (begin Bates number to end Bates number)
 - Relevant page numbers

FDA requests that load files containing metadata be submitted in a comma delimited ASCII text or spreadsheet format and be organized so that data fields will appear in the same order as they appear here (i.e., “Manufacturer filing the document” should be the first field, and “Relevant page numbers” should be the last field). Metadata load file delimiters should be as follows:

Metadata Load File Delimiters

Field separator:	Vertical Pipe (ASCII 124)
Field encapsulate:	Carat (ASCII 094)
Return value in data:	Tilde (ASCII 126)
Multi-value field:	Semi Colon (ASCII 059)
Dates format:	MM/DD/YYYY

Hard Returns should appear only at the end of each record.

If you scan paper documents for digital production, please use optical character recognition software (OCR) technology to render the images as functional text against the resulting PDF. Any extracted searchable text should be produced with the document as metadata.

The instructions in this enclosure are based on communications that FDA has received from industry and our evaluation of submissions received under the FD&C Act to date. If you have questions about how to prepare your submission, please contact us.

¹² If a responsive document is present in the University of California San Francisco Truth Tobacco Industry Documents library, that does not preclude it from this request.