AN UPDATE ON FDA'S COMPREHENSIVE PLAN ON TOBACCO AND NICOTINE

Mitch Zeller, J.D.
Director, FDA Center for Tobacco Products

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HOW CAN WE MAKE THE GREATEST IMPACT?

"We truly find ourselves at a crossroads when it comes to efforts to reduce tobacco use. But if we're going to meaningfully improve the public health, we need to be willing to take a hard look at our entire approach."

FDA Commissioner Dr. Scott Gottlieb

July 28, 2017

FDA'S NEW COMPREHENSIVE REGULATORY PLAN

ADDICTIVE NICOTINE IN COMBUSTIBLE CIGARETTES

"Nicotine, while highly addictive, is delivered through products on a continuum of risk...[and] the combustible cigarette is where nicotine's delivery vehicle leads to incredible amounts of disease and death."

FDA Commissioner Dr. Scott Gottlieb

October 19, 2017

FDA'S VISION FOR ADDRESSING NICOTINE

FDA envisions a world where **cigarettes would no longer create or sustain addiction**, and where **adults** who still seek nicotine could **get it** from alternative and **less harmful sources**

- Decrease the likelihood that future generations will become addicted to cigarettes
- Allow more addicted smokers to quit
- Encourage innovation of less harmful products for adults who need them
- Support innovations to medicinal nicotine and other therapeutic cessation products

FDA'S COMPREHENSIVE REGULATORY PLAN

To do this, we've designed a comprehensive package of actions for FDA to take which places ***nicotine*** – and the ***issue of addiction*** – at the center of regulatory efforts

All of the programmatic efforts are guided by several principles:

- Acknowledging that while highly addictive, nicotine is delivered through products on a ***continuum of risk*** and ***cigarettes*** are the ***most harmful***
- Striking an appropriate balance between ***smart regulation*** and encouraging ***innovation of satisfying, less harmful*** products
- Continuing to base all actions on ***regulatory*** and ***scientific foundation***

FDA'S COMPREHENSIVE REGULATORY PLAN

These efforts fall under several categories:

1) Regulatory Policies on Addiction, Appeal & Cessation

2) Youth Prevention Plan
   - Access & Marketing
   - Education

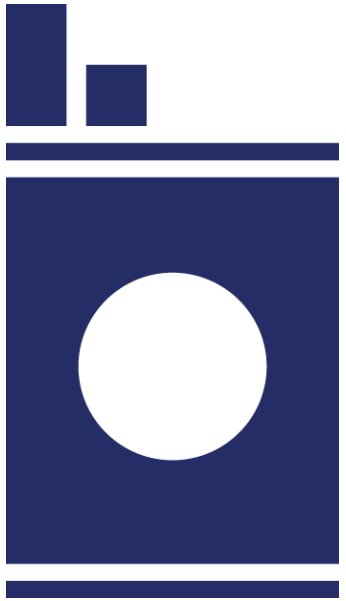
3) Science-Based Review of Novel Products

REGULATORY POLICIES ON ADDICTION, APPEAL & CESSATION

NICOTINE PRODUCT STANDARD ANPRM

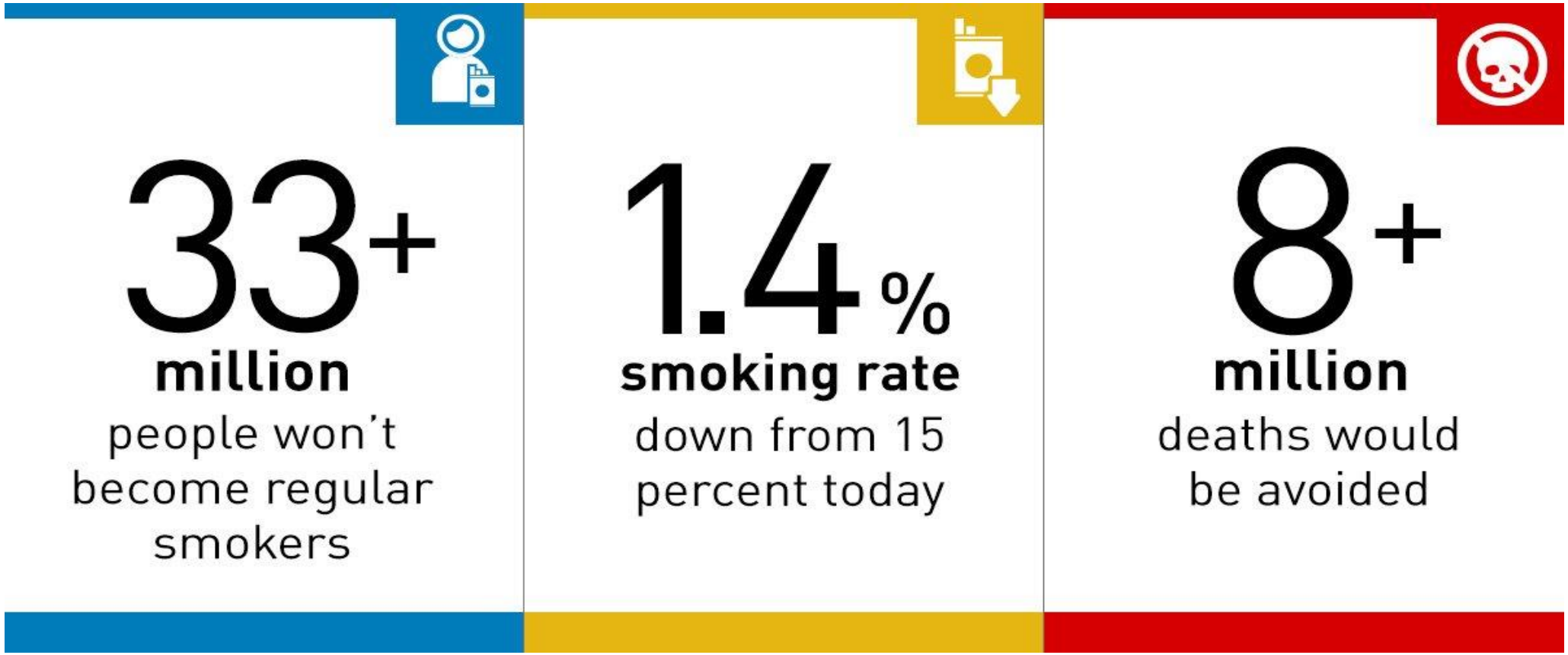
- On March 15, FDA issued the *Tobacco Product Standard for Nicotine Level of Combusted Cigarettes*, an Advance Notice of Proposed Rulemaking (ANPRM)

- Seeks public comment for consideration in developing a potential product standard to lower nicotine to a minimally or non-addictive level in cigarettes
  - What potential maximum nicotine level would be appropriate for the protection of the public health;
  - How a maximum nicotine level should be measured;
  - Whether such a product standard should be implemented all at once or gradually;
  - Whether a nicotine product standard should also cover additional combustible tobacco products; and
  - What unintended consequences might occur as a result of such a standard



ESTIMATES FROM ONE POSSIBLE NICOTINE PRODUCT STANDARD POLICY

Includes newly published estimates of one possible policy scenario to be realized by 2100:



ENCOURAGING A NATIONAL NICOTINE DIALOGUE

- Discuss core of the problem – but also the solution to addiction
- Engage public to educate and discuss:
  - **Correct common misperceptions**: Mistaken beliefs about nicotine and cancer
  - **Nicotine's role in continuum of risk**: Can be highly addictive; combustible cigarette is the delivery vehicle response for most disease and death; safe and effective in medicinal nicotine
  - **Nicotine and youth**: Potential for nicotine to rewire a teen's brain and create cravings leading to addiction; potential for future generations to not get addicted
  - **Adult smokers and nicotine**: How those who still want or need nicotine can get satisfying levels from other and less harmful sources
  - **Vulnerable populations**: Consider the impact on adult smokers with mental health disorders

PART 15 HEARING

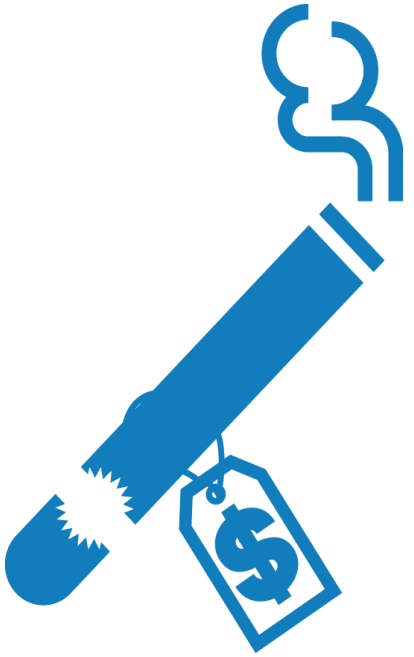
- FDA Nicotine Steering Committee formed in September 2017
  - Includes senior leaders from CDER, CTP & Office of the Commissioner
- Charged with re-evaluating and modernizing FDA's approach to the development and regulation of nicotine replacement therapy (NRT) products
  - Ensures alignment of FDA's centers and facilitates consensus and development of unified positions on cross-cutting issues
- Public hearing held in January 2018 to solicit comments on a variety of issues including:
  - New indications such as "Reduce to quit" for therapeutic product evaluation
  - Investigational New Drug Application vs Investigational Tobacco Product
  - Broadening NRT indications and flexibility on labeling
- Link to video of January hearing available on our website

FLAVORS IN TOBACCO PRODUCTS ANPRM

- On March 20, FDA issued *Regulation of Flavors in Tobacco Products*, an Advance Notice of Proposed Rulemaking (ANPRM)
- Seeking comments, research and data on:
  - Role flavors play in initiation & patterns of tobacco use, particularly among youth & young adults;
  - Role flavors may play in helping some adult smokers reduce cigarette use and/or switch to potentially less harmful tobacco products;
  - Consumer perceptions of health risks and addictiveness of flavored products;
  - Whether certain flavors used in tobacco products present potential adverse health effects to users or others

REGULATION OF PREMIUM CIGARS ANPRM

- On March 23, FDA issued *Regulation of Premium Cigars*, an Advance Notice of Proposed Rulemaking (ANPRM)
- Seeks scientific data on patterns of use and resulting public health impacts of “premium” cigars
  - The definition of “premium” cigars;
  - Use patterns of premium cigars generally and among youth and young adults specifically;
  - Public health considerations associated with premium cigars, including the health effects;
  - Studies or information regarding consumer perceptions of the health risks of premium cigars



YOUTH PREVENTION PLAN

YOUTH TOBACCO PREVENTION PLAN: ACCESS & MARKETING

- Last week, Commissioner Gottlieb announced a new focused segment of the Comprehensive Plan to reduce youth use of tobacco products, particularly 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."* – Commissioner Gottlieb, April 24, 2018

- The concern is the popularity of products that closely resemble a USB flash drive, have high levels of nicotine, and have emissions that are hard to see
  - These characteristics may facilitate youth use by making products more attractive to youth
  - Several of these products fall under the JUUL brand, but other brands with similar characteristics are emerging (myblu and KandyPens)

- Kids may be trying these products and liking them without knowing they contain nicotine

YOUTH TOBACCO PREVENTION PLAN: ACCESS & MARKETING

To address these concerns, FDA announced several new enforcement and regulatory steps:

- In April, conducted a large-scale, undercover nationwide “blitz” of brick-and-mortar & online retailers
- Since March, issued 40 Warning Letters to retailers for selling JUUL to minors
- So that FDA may better understand the reportedly high rates of youth use and appeal, sent official request for information to JUUL Labs requiring them to submit important documents on:
  - Product marketing
  - Research on health, toxicological, behavioral or physiological effects of the product, including:
    - Youth initiation and use
    - Whether certain design features, ingredients, or specifications appeal to different age groups
    - Youth-related adverse events and consumer complaints
- Worked with eBay to remove listings for JUUL on its website and voluntarily implement new measures to prevent new listings

YOUTH TOBACCO PREVENTION PLAN: ACCESS & MARKETING

- On May 1, FDA and the Federal Trade Commission (FTC) issued 13 warning letters to manufacturers, distributors, and retailers for selling e-liquids used in e-cigarettes with labeling and/or advertising that cause them to resemble kid-friendly food products
  - E-liquids resembled juice boxes, candy, cookies, and some included cartoon-like imagery
  - Several of the companies were also cited for illegally selling the products to minors

YOUTH TOBACCO PREVENTION PLAN: ACCESS & MARKETING

- Products are considered in violation of the Federal Food, Drug, and Cosmetic Act because their labeling and/or advertising imitating kid-friendly foods is false or misleading.
  - The FTC jointly-issued the letters because Section 5 of the Federal Trade Commission Act prohibits unfair or deceptive advertising
- Companies are directed to inform each agency of the specific actions taken to address each agency's concerns within 15 working days – failure to correct may result in further action(s)

YOUTH TOBACCO PREVENTION PLAN: EDUCATION

- *This Is Our Watch* educates retailers, clerks and the public on how to comply with federal tobacco laws by providing free materials
- Retailers who comply with laws that prohibit the sale of tobacco products to youth are important intervention points for preventing underage use
- Even though there are existing industry programs like *We Card*, retailers want FDA to explain how to comply with federal regulations
- Printed materials mailed to 350,000+ tobacco retailers and available online for download, sharing and self-printing

YOUTH TOBACCO PREVENTION PLAN: EDUCATION

- As part of FDA's regulatory efforts, we have several targeted public education campaigns aimed at educating at-risk teens about the harmful effects of tobacco, including *Fresh Empire* and *This Free Life*

- "The Real Cost," FDA's general market campaign, has prevented nearly 350,000 youth aged 11 to 18 nationwide from smoking from 2014 to 2016

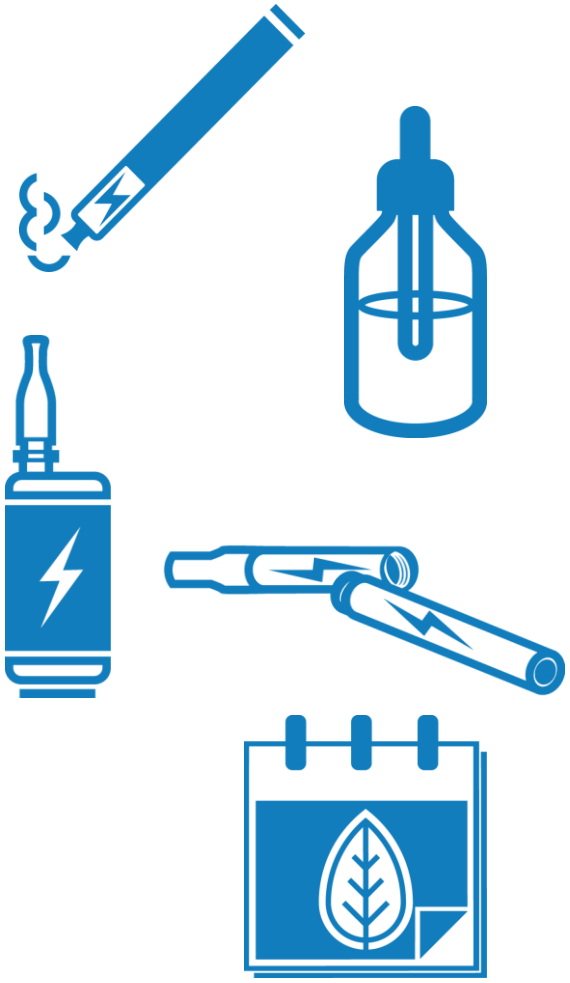
- For the first time, FDA is expanding *The Real Cost* to include messaging on electronic nicotine delivery systems (ENDS)
  - Initial messaging launched in Oct.
  - Full-scale effort in Fall 2018

YOUTH TOBACCO PREVENTION PLAN: EDUCATION

SCIENCE-BASED REVIEW OF NOVEL PRODUCTS

USING SCIENCE TO REVIEW AN EVOLVING MARKETPLACE

- Since June 2009, FDA has regulated cigarettes, smokeless and roll-your-own tobacco products
- In August 2016, FDA's regulatory authority over all other tobacco products – including electronic nicotine delivery systems (ENDS) – became effective (AKA "deeming")
- Evolving marketplace has seen rise in popularity of certain products like JUUL
- The challenge for all of us…products that are potentially less harmful but enticing to kids



REVISED APPLICATION DEADLINES FOR DEEMED PRODUCTS

Type	Example	Date
Combustible	Cigars, pipe tobacco, hookah tobacco	**Aug. 8, 2021**
Non-combustible	E-cigarettes and other ENDS, gels, certain dissolvables	**Aug. 8, 2022**

REVISED APPLICATION DEADLINES FOR DEEMED PRODUCTS

- Deadlines were revised to enable FDA to have the latest science and to put regulations, guidances and foundational rules in place before reviewing product applications, e.g.:
  - Product standards (exploding batteries, accidental exposure)
  - Rules for pathway submissions (SE, PMTA, MRTP)
  - Guidance for industry (PMTA for ENDS Final Guidance)
- Will make the review process more efficient, predictable and transparent while upholding our public health mission
- All applications will be required to meet regulations issued between now and the deadline

REVIEWING PRODUCTS IN EVOLVING TOBACCO MARKETPLACE: *IQOS* MODIFIED RISK APPLICATIONS

- Pending applications for new and potentially innovative products such as “heat-not-burn”
- Most well-known as proprietary technology of Philip Morris International (PMI), sold as “*iQOS*”
- Claims to heat tobacco – rather than burn – to reduce or eliminate formation of many harmful compounds associated with combustion
- Currently sold in high volumes in Japan, less so in Europe – not legally available in U.S.
- In May 2017, FDA filed three MRTP applications for scientific review from PMI for its *iQOS* system and three *HeatStick* products
- The applicant requests modified risk orders to market these products as follows:
  - The IQOS system heats tobacco but does not burn it
  - This significantly reduces the production of harmful and potentially harmful chemicals
  - Scientific studies have shown that switching completely from cigarettes to the IQOS system can reduce the risks of tobacco-related diseases

REVIEWING PRODUCTS IN EVOLVING TOBACCO MARKETPLACE: *IQOS* MODIFIED RISK APPLICATIONS

- TPSAC meeting held Jan. 24-25 for nine members to vote on nine questions
- The TPSAC votes are non-binding recommendations
- Comment period on applications is open-ended
- Our Office of Science will continue its review of these modified risk claims. Any applications for market authorization would be reviewed separately.
- Our responsibility is to assess the “net” impact on the population
- Concerns about teens and nicotine in any form remain

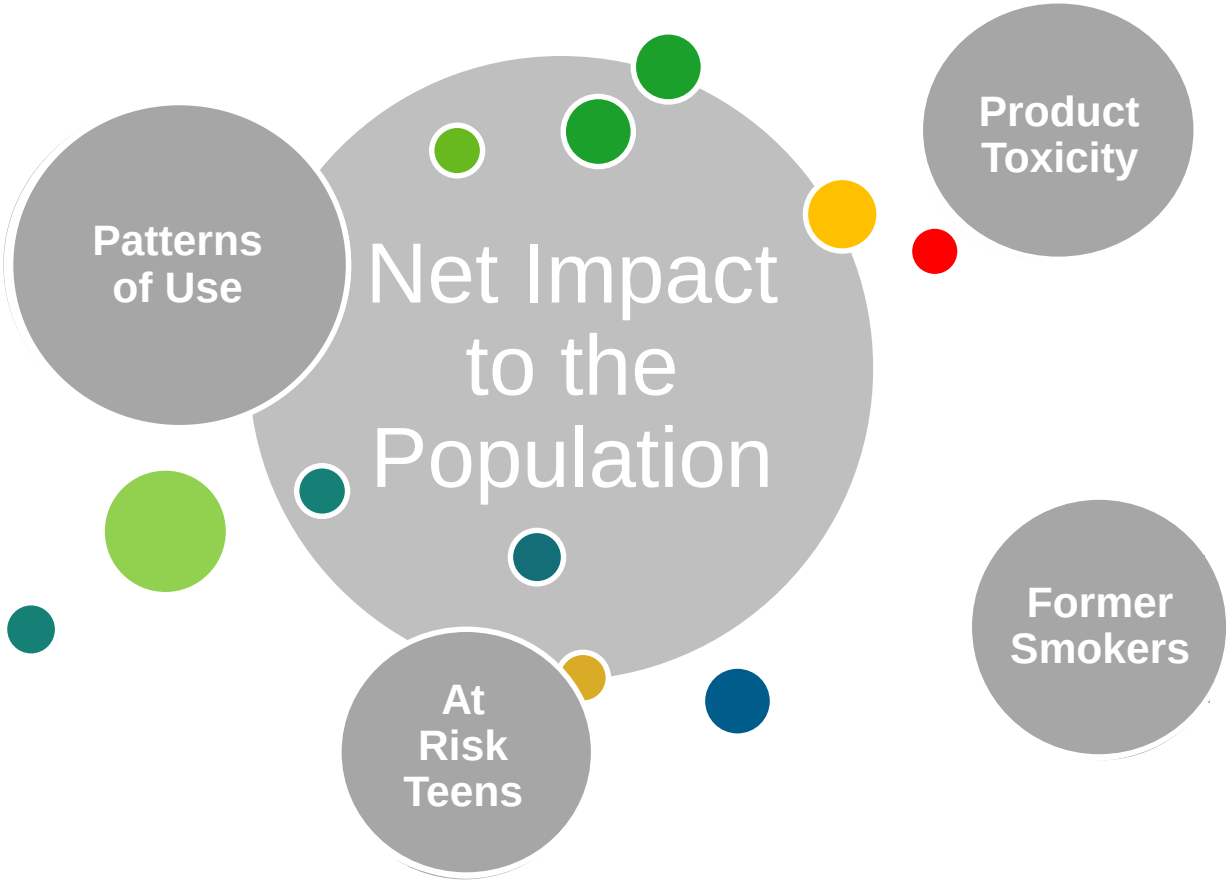
REVIEWING PRODUCTS IN EVOLVING TOBACCO MARKETPLACE: CAMEL SNUS MODIFIED RISK APPLICATIONS

- R.J. Reynolds Tobacco Company submitted MRTP applications for smokeless tobacco products:
  - Camel Snus Frost
  - Camel Snus Frost Large
  - Camel Snus Mellow
  - Camel Snus Mint
  - Camel Snus Robust
  - Camel Snus Winterchill

- Applications are open for public comment by June 18, 2018

- TPSAC meeting not yet scheduled

FDA'S STANDARD: ASSESSING OVERALL IMPACT TO PUBLIC HEALTH



QUESTIONS?

THANK YOU

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