Empowering Public Health to Influence Federal Regulation

PUBLIC HEALTH LAW CENTER
at Mitchell Hamline School of Law

SPEAKERS

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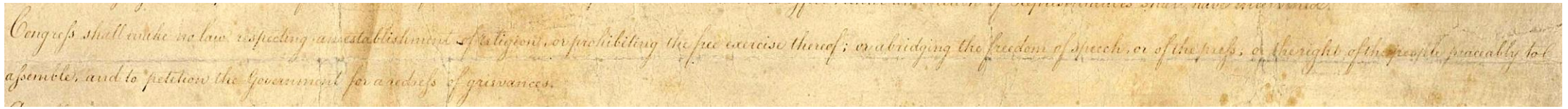
CITIZEN PETITIONS

- What are they and why are they useful?
- FDA tobacco regulation overview
- Menthol citizen petition example

CITIZEN PETITIONS: WHAT ARE THEY?



"Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances."

CITIZEN PETITIONS: WHAT ARE THEY?

5 U.S.C. § 553(e)

Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

CITIZEN PETITIONS: WHAT ARE THEY?

21 C.F.R. § 10.30

- Action Requested:
  - Request "to issue, amend, or revoke a regulation" including the "exact wording" of the existing and proposed regulations
  - Request to take "any other form of administrative action"
- Statement of Grounds
  - Factual and legal grounds on which the petitioner relies

CITIZEN PETITIONS: WHAT ARE THEY?

21 C.F.R. § 10.30

- Can be submitted by “a person who is not a citizen of the United States”
- Can be submitted electronically
- Petitions open a docket on regulations.gov

CITIZEN PETITIONS: WHY ARE THEY USEFUL?

21 C.F.R. § 10.30

- FDA shall respond "within 180 days of receipt of the petition"
- FDA will either: 1) approve the petition and take appropriate action; 2) deny the petition; 3) dismiss the petition if moot; or 4) provide a tentative response

CITIZEN PETITIONS: WHY ARE THEY USEFUL?

5 U.S.C. § 706

The reviewing court shall

compel agency action unlawfully withheld or unreasonably delayed

FDA TOBACCO REGULATION

FDA TOBACCO REGULATION

June 22, 2009

The Family Smoking Prevention and Tobacco Control Act is signed into law.

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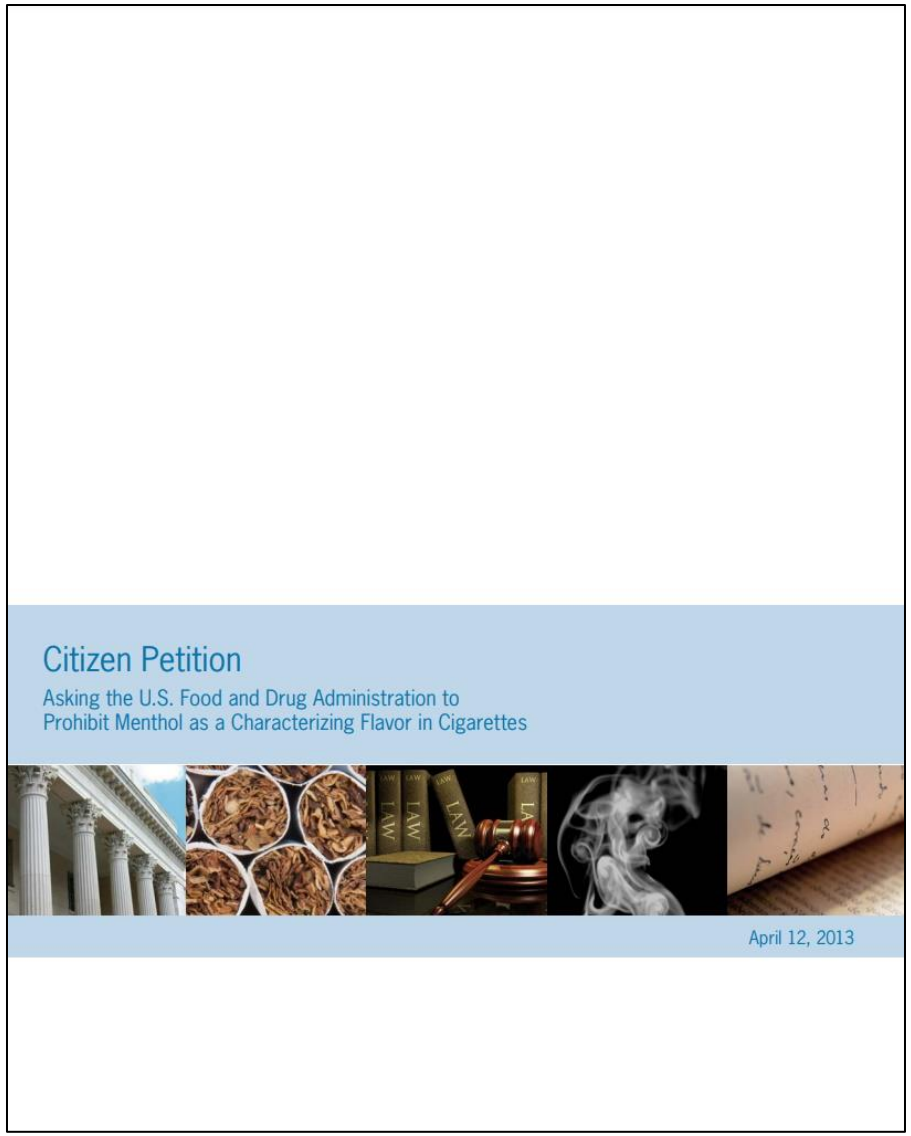
FDA TOBACCO REGULATION

21 U.S.C. § 387g(a)(1)(2)
a cigarette or any of its component parts ... shall not contain, as a constituent . . . or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, ... that is a characterizing flavor of the tobacco product or tobacco smoke.

FDA TOBACCO REGULATION

21 U.S.C. 387g(e)(1)
Immediately upon the establishment of the Tobacco Products Scientific Advisory Committee …, the Secretary shall refer to the Committee for report and recommendation …, the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities.

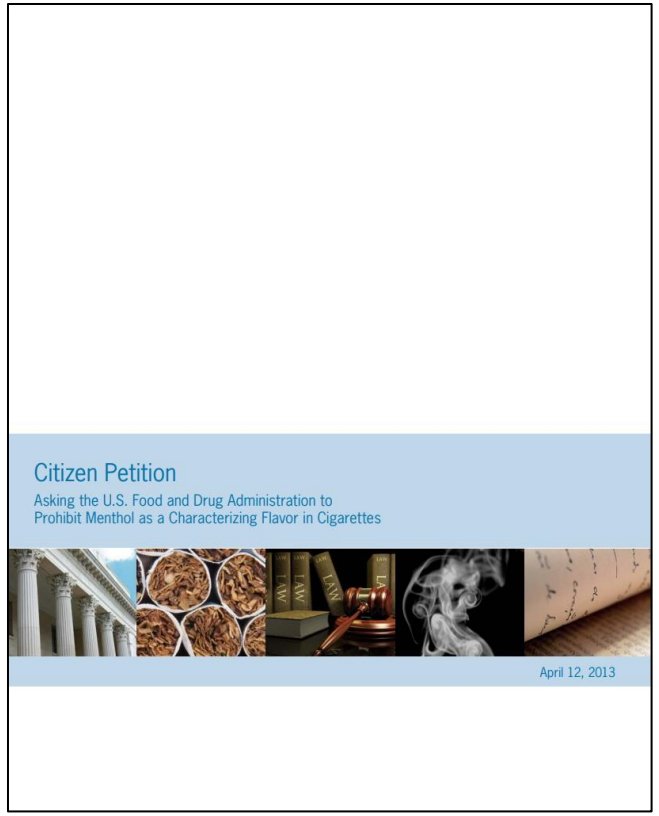
MENTHOL CITIZEN PETITION



MENTHOL CITIZEN PETITION

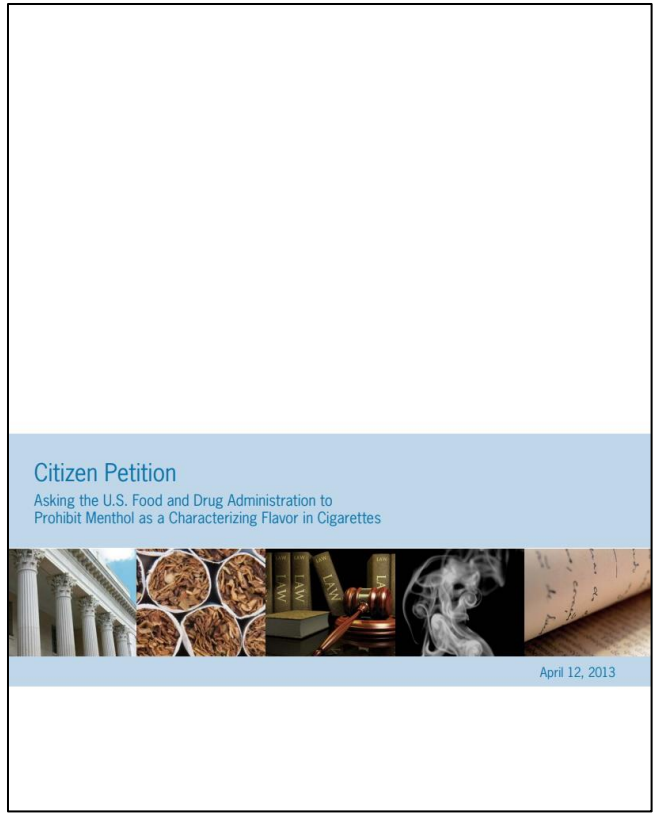
Action Requested:
"Add menthol to the list of additives and constituents in the prohibition on characterizing flavors in cigarettes and cigarette smoke."

Statement of Grounds:
Hundreds of scientific studies including the conclusions of the FDA's advisory committee that "removal of menthol cigarettes from the marketplace would benefit public health in the United States."



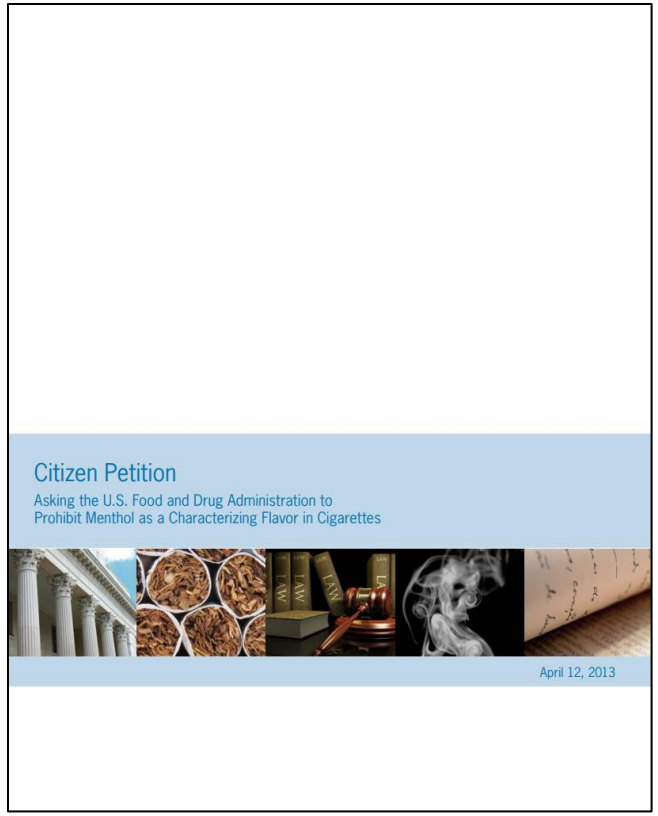
MENTHOL CITIZEN PETITION

- April 2013 – The Public Health Law Center, the Center for Black Health and Equity, the African-American Tobacco Control Leadership Council, and other public health groups file a citizen petition with the FDA, requesting the removal of menthol.
- July 2014 – FDA issues its own scientific report on menthol that also concludes the removal would benefit public health. The agency also issues an ANPRM, requesting information on menthol.
- March 2018 – FDA issues another ANPRM, requesting information on flavors in all products, including menthol in cigarettes.
- June 2020 – AATCLC sues the FDA for inaction on the 2013 citizen petition.
- January 2021 – PHLC files a supplement to the menthol citizen petition.
- April 2021 – FDA announces it will grant the citizen petition.



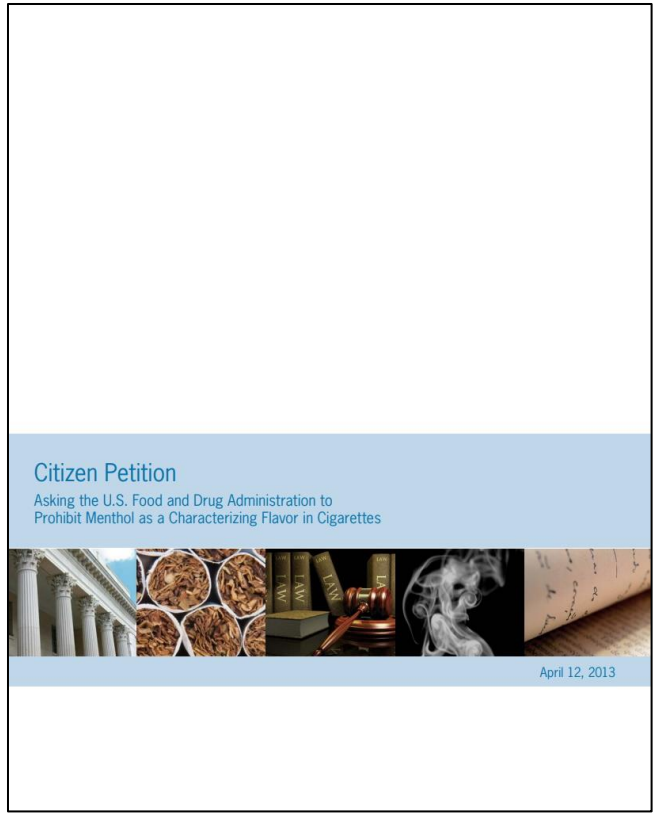
MENTHOL CITIZEN PETITION

- The petition was granted but no rule has been finalized or even proposed.
- The government believes that the litigation compelling action is moot and does not want to be bound by a deadline.
- The plaintiffs want the court to retain jurisdiction and impose deadlines for action.



MENTHOL CITIZEN PETITION

- Know the agency's standard for action
- Be thorough when you file with an eye towards future litigation
- Build a coalition that includes groups ready to litigate inaction
- Periodically update the record with new relevant information



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Empowering Public Health to Influence Federal Regulation:

Food Security

Preview:

- ❑ Public Input Impact
- ❑ Public Input Examples
- ❑ Takeaways

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HEALTHY FOOD POLICY PROJECT

Database of local laws and policies that

promote and support healthy food access

Some of our resources supporting healthy food access:

Policy Drafting Companion Guide

Authentic Resident Engagement

COVID-19 Food Access Policy Database

www.healthyfoodpolicyproject.org

FEDERAL FOOD SECURITY REGULATION

- USDA Food and Nutrition Service (FNS) regulations
- FDA Center for Food Safety and Applied Nutrition (CFSAN) regulations
- Health and Human Services regulations affecting FDA (e.g., SUNSET rule)
- As applicable, related regulations in USDA, FDA, and other agencies

Public Input Impact: Food Security

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SNAP WORK REQUIREMENT CHANGES
PUBLIC COMMENT & LITIGATION IMPACT

SNAP: Requirements for Able-Bodied Adults Without Dependents (12/5/2019), 84 FR 66782

- SNAP work requirement changes would have impacted nearly 700,000 unemployed individuals
- Over 100,000 comments submitted (majority form letters; ~25% unique/substantive)
- *DC v. USDA, Bread for the City v. USDA:* DC Circuit vacated agency rule after finding inadequate notice of final rule and failure of agency to appropriately address comments

Public comment impact: rule "arbitrary and capricious" for failing to appropriately address comments

- Comments re: multiple cost impacts on states not analyzed by agency in Regulatory Impact Analysis
- Comments re: quantifiable disparate impact of the rule not considered by agency in Civil Rights Impact Analysis

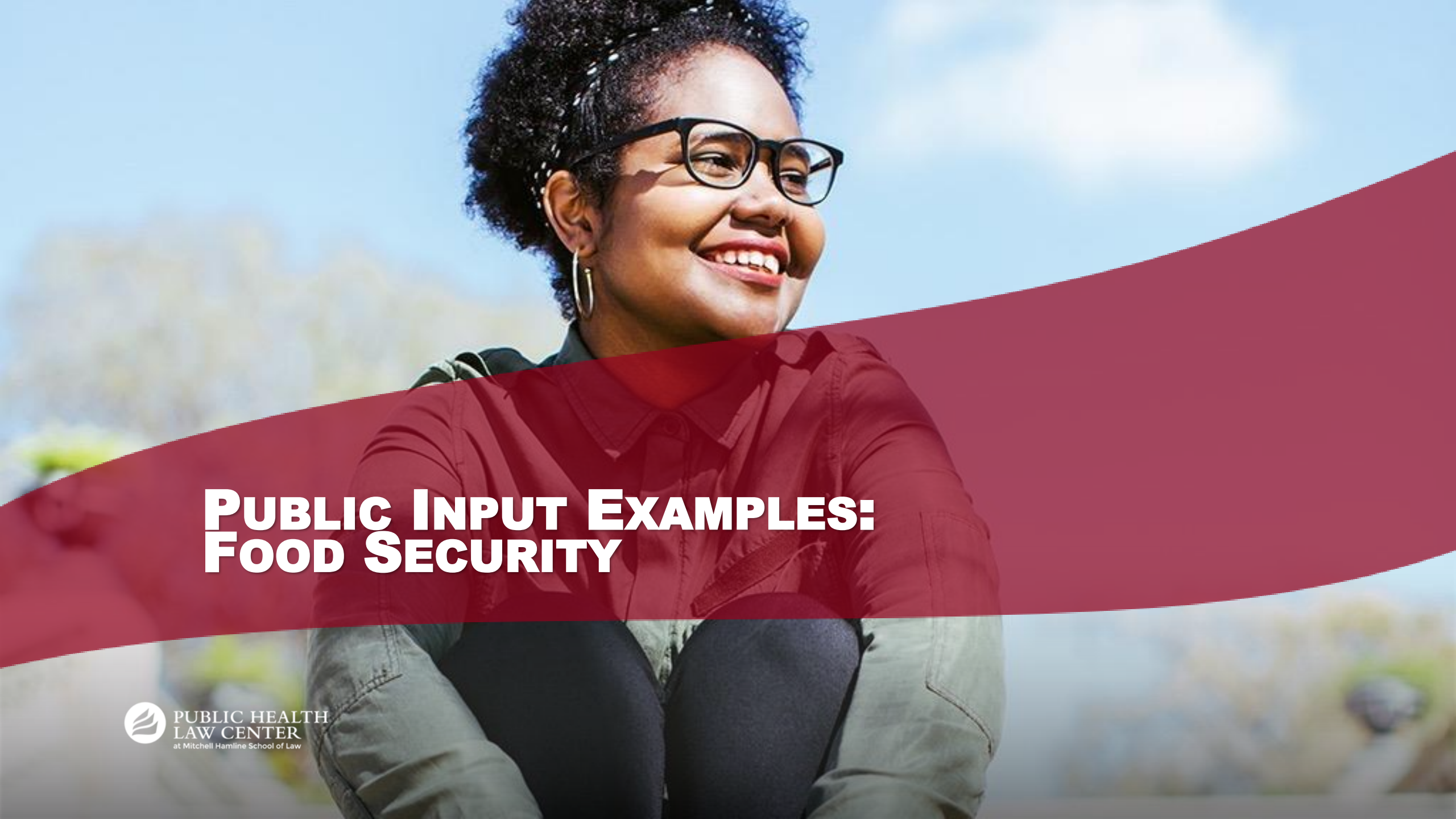
Litigation impact: enforced notice-and-comment requirements and consideration of public comment

CHILD NUTRITION PROGRAM STANDARDS
LITIGATION IMPACT

Child Nutrition Programs: Flexibilities for Milk, Whole Grains, and Sodium Requirements (12/12/2018), 83 FR63775

- USDA rule eliminated 100% whole grain requirement and rolled back sodium-reduction targets in school meals
- Over 86,000 comments submitted (majority form letters; nearly 2,000 unique/substantive)
- *CSPI, Healthy School Food Maryland v. Perdue*: District of Maryland vacated agency rule after finding final rule was not logical outgrowth of interim final rule

Litigation impact: enforced requirement to provide sufficient public notice of agency action



Public Input Examples: Food Security

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ENGAGEMENT EXAMPLES

- USDA Proposed Rule: *Simplifying Meal Service and Monitoring Requirements in the National School Lunch and School Breakfast Programs* (FNS-2019-0007)
- PHLC's public comment addressed:
  - Rule's rollback of nutritional improvements in school meals following 2012 improvements in nutrition standards
  - Rule's harm of children at risk of food insecurity
  - Agency's failure to consider disparate impacts on children of color in Civil Rights Impact Statement despite empirical data on program participation rates
  - Agency's failure to meaningfully consult Tribal governments as required by law

ENGAGEMENT EXAMPLES

- HHS Proposed Rule: *Securing Updated and Necessary Statutory Evaluations Timely* (HHS-OS-2020-0012)
- PHLC's public comment addressed how the rule:
  - Violates the APA by broadly imposing automatic expiration of Department regulations
  - Is arbitrary and capricious and violates statutory requirements in automatic expiration of regulations without adherence to APA procedural requirements or reasoned deliberation
  - Creates substantial uncertainty in public health and welfare regulation

ENGAGEMENT SUGGESTIONS

- Match expertise and potential bases for judicial review if the rule is finalized:
  - Provide evidence related to important aspects of the rule and its effects that requires agency consideration
  - Emphasize issues that can provide a basis for arguing a final rule is arbitrary and capricious for failure to address these issues (see earlier example where CRIA and RIA were insufficient)
  - Public health lawyers should raise any APA procedural deficiencies
- Limit topics addressed in comment to individual/agency capacity based on timeline
- Coordinate with other commenters

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THE OHIO STATE UNIVERSITY

MORITZ COLLEGE OF LAW

Empowering Public Health to Influence Federal Regulation

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Faculty Member, Drug Enforcement and Policy Center

Faculty Member, The James Comprehensive Cancer Center

The Ohio State University

Disclosures & Disclaimer

Expert witness retained by the Direct Purchaser Class Plaintiffs in In re Suboxone Antitrust Litigation, No. 2:13-MD-2445 (E.D. Pa)

Expert witness retained by the Direct Purchaser Class, End Payor Class, and Retailer Plaintiffs in In re Opana Antitrust Litigation, No. 14cv-10150 (N.D. Ill.)

Honoraria for academic workshops and presentations from the Gray Center for the Study of the Administrative State and the Law & Economics Center at George Mason University Antonin Scalia Law School and The Ewha Institute for Biomedical Law & Ethics at Ewha Women's University

This presentation is for informational and educational purposes only, and is not legal advice.

The Importance of Public Comment to the FDA

Anyone can submit comments concerning new rules and regulations being considered by the Food and Drug Administration. And these suggestions can, and do, influence the agency's actions.

The FDA regulates the way that foods, drugs, medical devices, and other health products are produced and sold. FDA regulations have considerable impact on the nation's health, industries, and economy. Violators can be fined, jailed, or forced to close their businesses. FDA regulations are issued consistent with the Administrative Procedures Act, which governs the rulemaking process for federal agencies. The FDA encourages public comment on the agency's proposed rules because the public has a vested interest in the products it regulates, and because the input provides critical insight into the effects of the regulation on the public. The comments often present the "real world" concerns of those who use the products.

For example, several years ago nutritionists, bread manufacturers, and consumer groups provided comments on which ingredients Americans wanted--or didn't want--in white bread. The FDA adopted the standards only after taking into account the public's comments and recommendations. The FDA allows ample time for public input and carefully considers these comments when it draws up a final rule. "People don't always understand that FDA's decisions in response to comments aren't just based on the number of comments, or 'majority rules,'" says Edwin V. Dutra Jr., director of the FDA's Regulations Policy and Management Staff. "When a consumer sends in a comment based on sound grounds, that comment can definitely make a difference in the agency's decision-making."

Opportunities for public comment include . . .

- Notice-and-comment rulemaking (to promulgate regulations, like FDA's Deeming Rule)
- Draft guidance documents
- Advisory Committee meetings
- Other public meetings and workshops

What is an Advisory Committee?

- "any committee, board, commission, council, conference, panel, task force, or other similar group . . . which is--(A) established by statute or reorganization plan, or (B) established or utilized by the President, or C) established or utilized by one or more agencies, in the interest of obtaining advice or recommendations . . ." 5 U.S.C. app. § 3.

- Governed by the Federal Advisory Committee Act (FACA) and implementing regulations at 41 CFR parts 101-6 and 102-3 (General Services Administration's regulations) and 21 CFR part 14 (FDA's regulations).

POLITICO

HEALTH CARE

FDA panel votes against broad rollout of Pfizer booster shot, endorses narrower use

The panel unexpectedly broke with the Biden administration's push for a widespread booster campaign this fall.

The FDA panel's votes, while non-binding, are an unexpected roadblock for the Biden administration's plan to begin administering boosters widely. | Emily Elconin/Getty Images

By LAUREN GARDNER
09/17/2021 02:17 PM EDT

https://www.politico.com/news/2021/09/17/tensions-rise-as-fda-advisory-panel-weighs-evidence-on-pfizer-booster-512543

Why are Advisory Committees important?

- Advisory Committee recommendations are *purely* advisory and non-binding

- But FDA often follows recommendations

  See, for example: Zhang AD, Schwartz JL, Ross JS. Association Between Food and Drug Administration Advisory Committee Recommendations and Agency Actions, 2008-2015. Milbank Q. 2019 Sep;97(3):796-819. doi: 10.1111/1468-0009.12403.

- And meetings and materials are open to the public, and an important transparency opportunity

What are some paths to influence?

- Open public hearing portion of meetings
- Written comments submitted via regulations.gov

ce Documents / The Open Public Hearing at FDA Advisory Committee Meetings

GUIDANCE DOCUMENT

The Open Public Hearing at FDA Advisory Committee Meetings

Guidance for the Public, FDA Advisory Committee Members, and FDA Staff

MAY 2013

Download the Final Guidance Document

Final

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Issued by: Office of the Commissioner

The Food and Drug Administration's (FDA's) advisory committees play an essential role in FDA's activities to protect and promote public health through the regulation of human and animal drugs, biological products, medical devices, foods, and tobacco products. FDA's

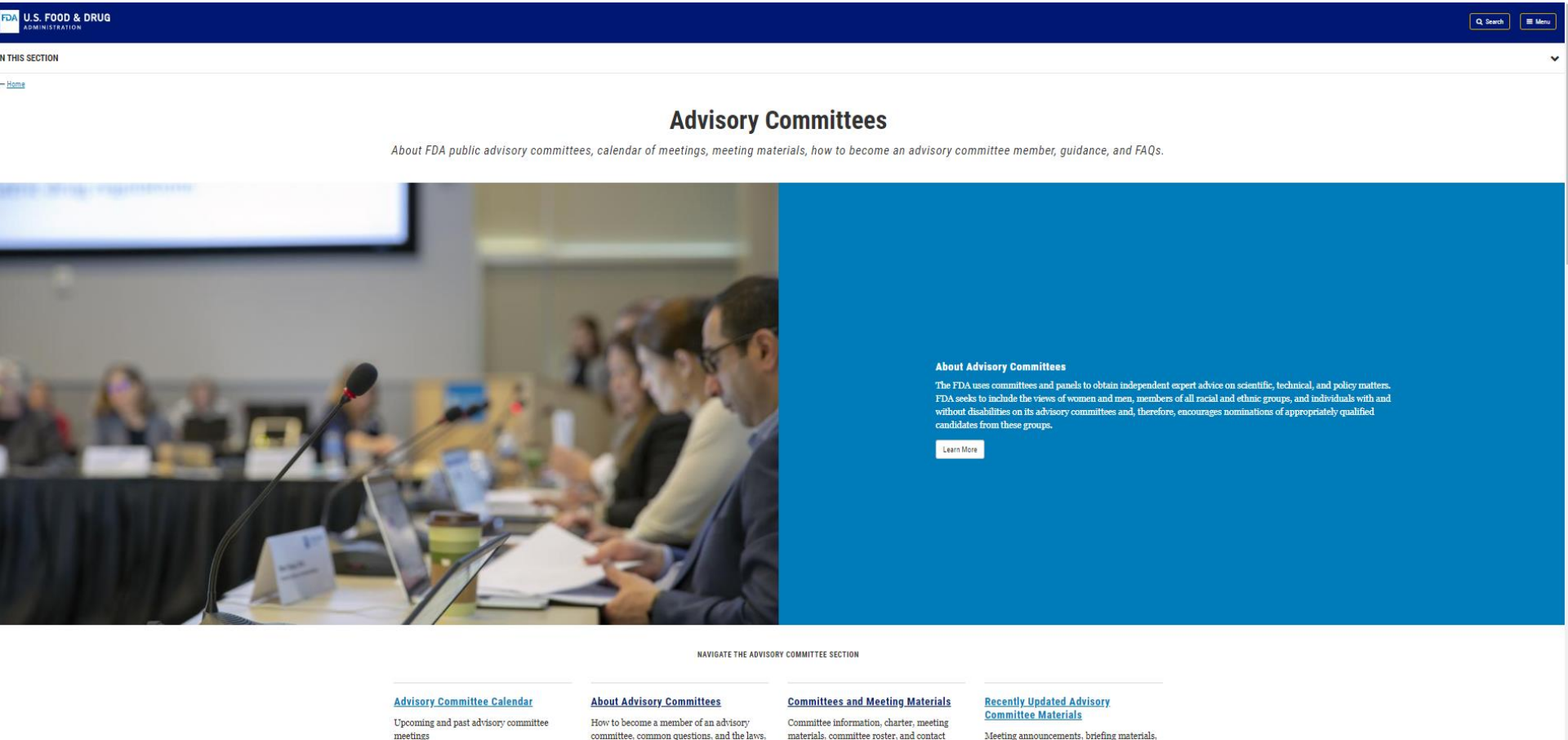
(Nominating members is another possibility!)

https://www.fda.gov/advisory-committees/advisory-committee-membership/applying-membership-fda-advisory-committees

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/advisory-committee-guidance-documents

Resources

- Information on FDA's website: https://www.fda.gov/advisory-committees



Resources

- Information on FDA's website: https://www.fda.gov/advisory-committees

- FDA's public meeting schedule: https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

29112 **Federal Register** / Vol. 84, No. 120 / Friday, June 21, 2019 / Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA–2019–N–2514]

Standards for Future Opioid Analgesic Approvals and Incentives for New Therapeutics To Treat Pain and Addiction; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA, Agency, we) is holding a public hearing on September 17, 2019, entitled ''Standards for Future Opioid Analgesic Approvals and Incentives for New Therapeutics to Treat Pain and Addiction.'' The Agency

WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 18, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 18, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date. You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the

2019–N–2514 for ''Standards for Future Opioid Analgesic Approvals and Incentives for New Therapeutics to Treat Pain and Addiction; Public Hearing.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including

Opportunities for public comment include . . .

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- Draft guidance documents
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Thanks!
Questions?

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