

CENTER FOR TOBACCO PRODUCTS



STRATEGIC PLAN

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I am pleased to introduce the U.S. Food and Drug Administration (FDA) Center for Tobacco Products' (CTP or the center) latest strategic plan, which outlines the center's programmatic and workforce initiatives for the next 5 years. This plan reflects the latest chapter in the center's history and will build upon a strong foundation that has been established and cultivated since its inception in 2009.

Over the past 14 years, the center has worked steadfastly to reduce the public health burden caused by tobacco product use, which remains the leading cause of preventable disease and death in the United States. We've maintained our commitment to implementing the components of the Family Smoking Prevention and Tobacco Control Act, while adapting to a complex and continually evolving tobacco landscape. Among other achievements, the center has published 50 Level 1 final guidance documents (i.e., those with new, or more than minor changes to, interpretations or policies on regulatory issues) and 16 final rules, made decisions on millions of applications for new tobacco products, prevented hundreds of thousands of young people from initiating tobacco product use through our "The Real Cost" campaign, and issued over 130,000 warning letters and over 30,000 civil money penalties to those violating the law. These accomplishments would not have been possible without the dedicated contributions of our center's staff, who have grown in number from less than 10 in 2009 to more than 1,100 in 2023.

As we look forward to the next 5 years, we recognize this as a critical moment in the history of tobacco product regulation in the United States. Guided by the goals and outcomes in this strategic plan, the center is collectively committed to issuing impactful regulations, using robust science to inform application reviews, pursuing timely and effective compliance and enforcement strategies, and educating the public about the risks of tobacco products. Interconnected across this programmatic work, we remain unwavering in our commitment to advance four key overarching themes that are common to all of the goals of the strategic plan: science, health equity, stakeholder engagement, and transparency. We will also continue to invest in our staff—our greatest resource—by continually advancing operational enhancements and supporting the further development of our highly qualified, inclusive, and high-performing workforce.

This roadmap for the future of CTP would not have been possible without the contributions of a diverse array of individuals, including staff from across the center and FDA, as well as external stakeholders who participated in the public comment opportunities focused on the strategic plan's scope and content. This valuable input, coupled with the strong foundation of the center's past achievements, position the center well for future success. As we embark on the next half decade, I am confident this strategic plan and our center's staff will continue to meaningfully advance our mission to make tobacco-related disease and death part of America's past, not our future.

Brian King, Ph.D., M.P.H.

Director, Center for Tobacco Products

INTRODUCTION

About the Center

The U.S. Department of Health and Human Services (HHS) U.S. Food and Drug Administration (FDA) Center for Tobacco Products (CTP) is responsible for implementing the Family Smoking Prevention and Tobacco Control Act (FSPTCA), which Congress passed in 2009. The FSPTCA provides broad authority to regulate the manufacturing, distribution, and marketing of tobacco products.

As a public health regulatory entity, CTP takes a cohesive, comprehensive approach to reduce the negative health effects caused by tobacco use. This approach helps achieve the center's goals of preventing people from starting to use tobacco products, encouraging people who use tobacco products to quit, and reducing the harm caused by tobacco product use.



The center's approach includes:



Issuing regulations and guidance to protect public health.



Undertaking actions to ensure tobacco product manufacturers and retail establishments comply with laws and regulations.



Reviewing tobacco product applications to uphold science-based regulatory standards.



Educating the public about the risks of using tobacco products and the benefits of cessation.

As of November 2023, CTP employs more than 1,100 staff. CTP's diverse workforce is highly qualified with education, experience, and skills in an array of scientific and technical fields. These staff are organized into six offices: Office of Regulations, Office

of Science, Office of Health Communication and Education, Office of Compliance and Enforcement, Office of Management, and Office of the Center Director. These offices work together to achieve CTP's overall vision and mission and the goals, outcomes,

objectives, and strategies set forth in this strategic plan. CTP is 100 percent funded by tobacco user fees, which are fees paid by manufacturers and importers of certain classes of tobacco products.

Vision and Mission

As part of the development of this strategic plan (also referred to as the plan), CTP reviewed and refreshed its vision and mission statements to reflect feedback received through the development process. This included highlighting the public health focus of the center's activities, consistent with the FSPTCA, and the importance of activities to advance health equity. Taken together, these statements reinforce the center's work to reduce the adverse health impacts of tobacco use, which remains the leading cause of disease, disability, and death in the United States.

Development of the Strategic Plan

In February 2023, the center began partnering with FDA's Office of Planning, Evaluation, and Risk Management on the overall strategic plan development process. Through May 2023, this included assessing the current vision and mission statements; planning internal and external engagement strategies; and considering potential cross-cutting themes, goal areas, outcomes, and objectives.

From May through August 2023, CTP engaged with center staff and external stakeholders to further define the draft plan's goals, outcomes, objectives, and strategies. Their insights, reflected throughout this plan, emphasized several topics, such as enhancing the clarity of regulatory communications and expectations for product applications, optimizing work processes, and ensuring cross-office coordination.

Employee engagement was obtained through listening sessions, an anonymous survey, a suggestion inbox, and regular updates from the center director during the process. Employees were asked to share their insights and perspectives on opportunities and challenges facing the center and how they may be addressed. Feedback included comments from 170

VISION

To make tobacco-related death and disease part of our nation's past by ensuring a healthier future and advancing health equity for those living in the United States.

MISSION

To protect the public health of the U.S. population from tobacco-related death and disease by comprehensively regulating the manufacture, distribution, and marketing of tobacco products; educating the public, especially youth, about the dangers of using tobacco products; and promoting and supporting strategies that ensure an equitable chance at living a healthier life for everyone.

participants across nine listening sessions and approximately 350 survey participants.

External stakeholder engagement included holding a public listening session and soliciting written comments. In July, CTP announced the virtual public listening session for stakeholders to provide verbal public comments on development of the plan. CTP shared proposed strategic goal areas, cross-cutting themes, and questions that it was soliciting feedback on. Shortly after, the [Federal Register notice](#) was issued announcing the public listening session and [establishing a docket \(FDA-2023-N-2873\)](#) to receive written comments. The docket remained open through the end of August.

On Aug. 22, 2023, CTP held a 6-hour virtual public listening session to hear stakeholder feedback on the proposed goal areas and cross-cutting themes for CTP's comprehensive strategic plan. All registrants who requested to speak at the public listening session were given up to 4 minutes to deliver their comments. During the public listening session, 59 external stakeholders provided verbal comments. A [transcript of the listening session](#) is publicly available.

In addition to feedback from the stakeholders at the public listening session, the docket received 2,436 written comments, of which 1,129 were identified as unique (125 substantive and 1,004 other unique comments); 1,299 were form letter copies of two different campaigns and eight were duplicate comments.

Comments provided varied perspectives on a broad spectrum of topics related to tobacco regulation, particularly highlighting the exchange of information between FDA and stakeholders (see Appendix A1). The feedback from external, as well as internal, stakeholders was incorporated into the plan's development and is reflected in the final plan.

Implementation of the Strategic Plan

In implementing this plan, CTP will regularly track and monitor progress and make timely and necessary adjustments to key activities or approaches. Linking strategic initiatives and desired outcomes to data and strong analytics will continue to support our productive, results-driven environment. The current regulatory environment in which CTP operates is very dynamic. In recognizing the evolving marketplace and pace of change, CTP will continue to evaluate its work supporting

implementation of the plan and accordingly update our approach to reflect challenges and maximize opportunities.

Specific activities stemming from the goals, outcomes, and objectives outlined in the plan will be announced as they are implemented over the coming months and years. Routine updates will be provided to the public on these activities, as appropriate.



STRATEGIC PLAN SUMMARY

Cross-Cutting Themes

In alignment with the center's vision and mission, CTP's Strategic Plan defines five goals, 10 outcomes, and several corresponding objectives. These goals are reinforced by four cross-cutting themes that are emphasized throughout the plan:



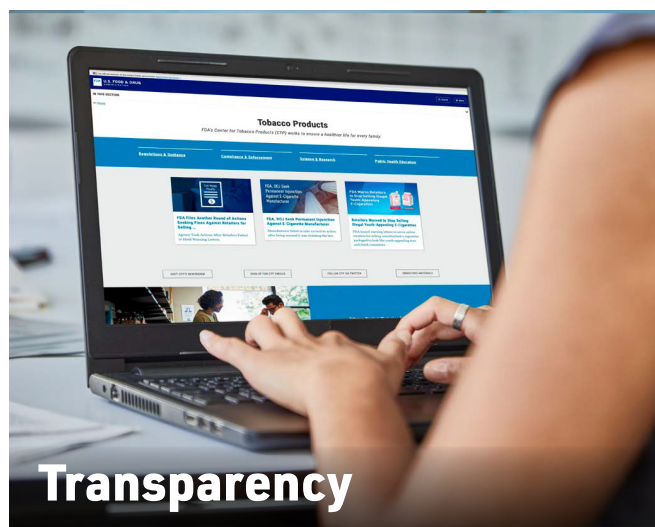
Maintaining our commitment to use data and evidence-driven approaches to inform CTP decision-making



Pursuing the highest level of health for all people by integrating health equity into CTP's programmatic, regulatory, policy, and operational activities



Continuously striving to optimize engagements with interested parties both external and internal to FDA, including other federal agencies



Promoting understanding of tobacco regulation through clear, consistent, and comprehensive communication

STRATEGIC PLAN: GOALS, OUTCOMES, AND OBJECTIVES

	GOALS	OUTCOMES	OBJECTIVES
1	 <p>Develop, Advance, and Communicate Comprehensive and Impactful Tobacco Regulations and Guidance</p>	<p>The Evolving Marketplace Is Comprehensively Regulated</p> <p>The Public and Stakeholders Are Aware of and Contribute to Regulations and Guidance</p>	<p>1.1 Develop and Implement a Cohesive Regulation and Guidance Agenda</p> <p>1.2 Advance Comprehensive and Impactful Regulations and Guidance</p> <p>1.3 Ensure That Tobacco Regulations, Guidance, and Related Public Statements Are Clear and Accessible</p>
2	 <p>Ensure Timely, Clear, and Consistent Product Application Review</p>	<p>Tobacco Product Applications Are Reviewed Using an Efficient, Transparent, and Consistent Process</p> <p>Marketing Decisions Are Supported by the Best Available Science</p>	<p>2.1 Identify, Develop, and Implement Processes That Achieve Application Review Efficiencies</p> <p>2.2 Ensure Clear Communication and Transparency Related to Tobacco Product Review Processes and Marketing Decisions</p> <p>2.3 Utilize the Best Available Science to Inform Decision-Making</p>
3	 <p>Strengthen Compliance of Regulated Industry Utilizing All Available Tools, Including Robust Enforcement Actions</p>	<p>Violative Tobacco Products, Particularly Those That Appeal to Youth, Are Not in the Marketplace</p> <p>Regulated Industry Is Educated on How to Be Compliant With the Law</p>	<p>3.1 Enhance Educational Resources That Facilitate Voluntary Compliance by Regulated Industry</p> <p>3.2 Pursue Timely and Impactful Compliance and Enforcement Strategies That Adapt to the Evolving Marketplace</p> <p>3.3 Collaborate With Other Federal and State Agencies on Compliance and Enforcement Strategies</p>
4	 <p>Enhance Knowledge and Understanding of the Risks Associated With Tobacco Product Use</p>	<p>The Public Receives Timely and Clear Health Communication and Education</p> <p>The Public Receives Evidence-Based Health Communication and Education</p>	<p>4.1 Educate Youth About the Risks of Tobacco Product Use</p> <p>4.2 Educate People Who Use Tobacco Products About the Benefits of Cessation</p> <p>4.3 Educate Adults Who Smoke About the Relative Risks of Tobacco Products</p>
5	 <p>Advance Operational Excellence</p>	<p>A Talented, Diverse, and Engaged Workforce is Attracted and Retained</p> <p>Business Operations Are Efficient and Effective in Supporting Programmatic Goals</p>	<p>5.1 Support and Further Develop a Highly Qualified, Inclusive, and High-Performing Workforce</p> <p>5.2 Ensure the Most Efficient and Effective Use of Financial Resources</p> <p>5.3 Continually Advance Operational Enhancements</p>

GOAL 1: **Develop, Advance, and Communicate Comprehensive and Impactful Tobacco Regulations and Guidance**



CTP is committed to developing and adhering to impactful tobacco regulations and guidance that are driven by science. As part of this commitment, CTP will develop a cohesive regulation and guidance agenda that will be updated annually, will continue to craft regulations and guidance that maximize public health benefits and promote industry compliance, and will ensure that public statements are in plain language and accessible.

OBJECTIVE 1.1

Develop and Implement a Cohesive Regulation and Guidance Agenda

CTP has devoted significant resources to developing and/or issuing a significant suite of regulations and guidance documents that have served as the foundation for tobacco regulation in the United States. This work has provided comprehensive parameters for tobacco regulation and has created a strong foundation on which to build future work. A significant focus of CTP's work going forward will be to fully implement these regulations and guidance documents and advance its regulatory agenda.

OUTCOMES

- **The Evolving Marketplace Is Comprehensively Regulated**
- **The Public and Stakeholders Are Aware of and Contribute to Regulations and Guidance**

In conjunction with this strategic plan, and informed by feedback from stakeholders, CTP developed and published its regulation and guidance agenda. It will be updated annually based on the center's periodic

assessment of this agenda, and continuous prioritizing, reprioritizing, and when appropriate, deprioritizing of certain activities to reflect its recent activities, decisions, and desired future outcomes along with the current state of the tobacco marketplace. This process will be guided by the best available science, strict adherence to the law, and our fundamental mission to protect and promote public health and provide the framework for the center's development and prioritization of regulations and guidance documents.

CTP's Office of Regulations and a dedicated policy unit in the Office of the Center Director will play pivotal roles in guiding this work. This will include ways to ensure deliberate and thoughtful development, scheduling, and implementation of regulations and guidance documents within and across CTP as well as with key partners in FDA and the federal government to advance tobacco regulation priorities.

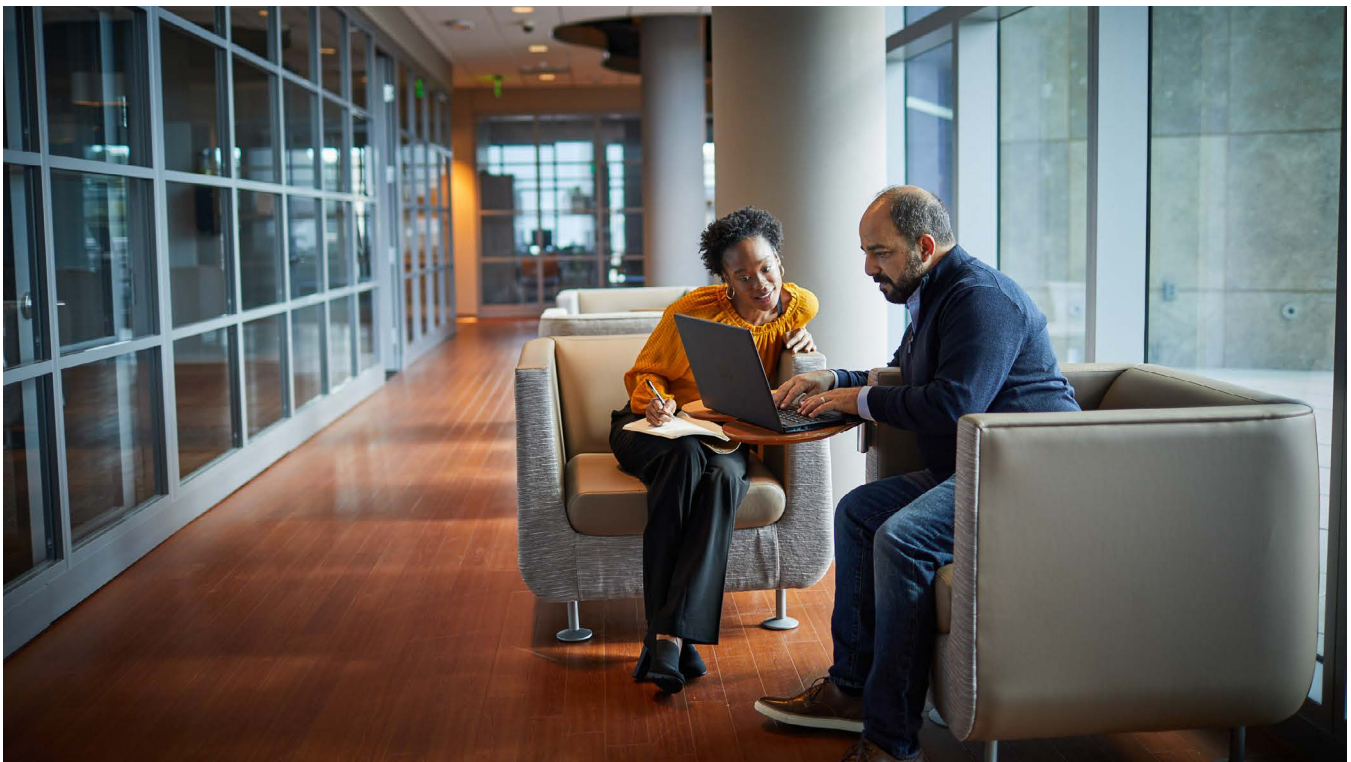
OBJECTIVE 1.2

Advance Comprehensive and Impactful Regulations and Guidance

CTP has issued regulations and guidance that advance the public health mission of the center to protect those living in the United States from tobacco-related disease and death.

Going forward, CTP will continue to develop and issue additional guidance documents and regulations that address premarket requirements, registration and listing, tobacco product testing, and compliance. Throughout the rulemaking and guidance development process, CTP will carefully consider the impact of tobacco product guidance documents and regulations on diverse stakeholder groups and on the ability to advance health equity.

In addition, CTP will communicate its rule and guidance agenda, in alignment with the administration's Unified Agenda of Federal



Regulatory and Deregulatory Actions, to help inform stakeholders of the center's priorities. The center will also seek other ways to communicate with stakeholders, for example, through use of listening sessions and public meetings. Further, CTP will aim to optimize internal work processes and to ensure tools and resources that support policy implementation and compliance are available to our employees. For example, as funding permits, the center will aim to use information technology (IT) solutions to better track status and progress on activities in an integrated and coordinated manner.

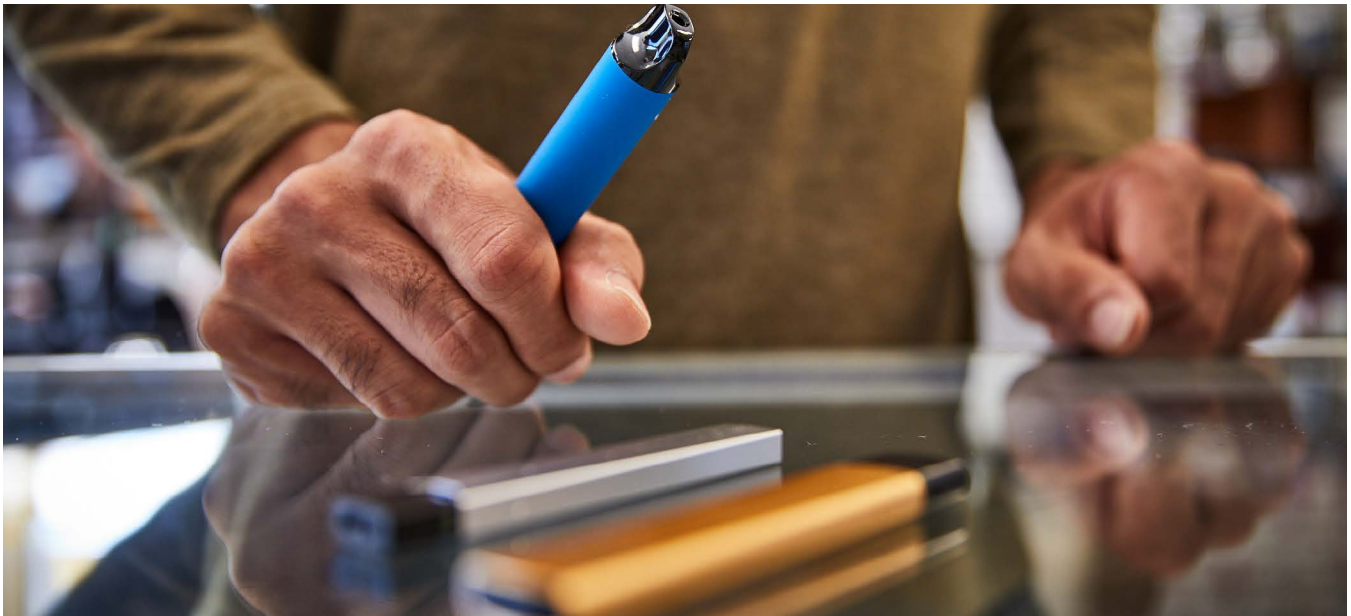
OBJECTIVE 1.3
Ensure That Tobacco Regulations, Guidance, and Related Public Statements Are Clear and Accessible

To ensure CTP's portfolio of regulations and guidance documents is well-understood and communicated clearly, the center will seek input from internal and external stakeholders, as appropriate, at various points throughout the policy development promulgation processes. CTP will take a range of steps to ensure the portfolio of regulations and guidance documents is well-understood, communicated clearly, and benefits from early feedback, as appropriate. For example, in accordance with government-wide practice, CTP will continue to identify regulations that are under consideration in the Unified Agenda of Federal Regulatory and Deregulatory Actions, which is updated twice a year by each presidential administration and is available to the public.

In addition to this continued work, CTP intends to proactively engage with stakeholders using meetings or *Federal Register* notices to solicit feedback and comments from the public on a more regular basis on needed rules and guidance documents.

Similarly, the center will continue to use public meetings as appropriate when issuing proposed rules to provide an overview of the rules and to expand direct engagement with the public, including affected communities. The center's intent is to ensure public meetings give stakeholders sufficient opportunities to deliver comments in an open forum that provides a broad representation of ideas and perspectives. A well-regulated marketplace depends on access to accurate and authoritative regulatory communications. CTP is committed to cultivating a well-informed, shared understanding of the tobacco product regulatory landscape; and to further building national awareness and understanding of CTP regulations and guidance, and to fostering relationships with stakeholders. The center will continue to develop and disseminate communications across numerous platforms, including the CTP Newsroom, social media hubs, and the CTP website, which explain CTP's regulatory actions and their benefits.

GOAL 2 : **Ensure Timely, Clear, and Consistent Product Application Review**



CTP remains steadfast in ensuring that consumers are protected from tobacco products that do not meet regulatory standards. Efficient and effective review processes are paramount to achieving the center's public health goals. CTP will leverage experience gained from reviewing premarket tobacco product applications for millions of products to make enhancements to the review process that will foster greater accountability and transparency. To complement these enhancements, CTP will also continue to advance its tobacco regulatory science program to further support evidence-based decision-making.

OBJECTIVE 2.1 **Identify, Develop, and Implement Processes That Achieve Application Review Efficiencies**

CTP has managed an unprecedented volume of applications for over 26 million products in a 3-year period. To accomplish this task, CTP developed and implemented approaches designed to provide an efficient and consistent review process. Due to changes in the regulatory and legal landscape and lessons learned from processing applications for tens of millions

OUTCOMES

- **Tobacco Product Applications Are Reviewed Using an Efficient, Transparent, and Consistent Process**
- **Marketing Decisions Are Supported by the Best Available Science**

of products, the center has identified opportunities to achieve additional efficiencies and continue to enhance

communication with applicants. For example, through the review of applications, CTP has identified common challenges during the review cycle and is committed to developing and implementing strategies to further enhance the consistency and efficiency of the review process. Strategies include the following:

- Help ensure that CTP receives product applications of sufficient quality at the acceptance review stage, including by developing and implementing a validation tool to ensure that the information provided in required forms is present and complete prior to application submission.
- Work to provide scientific reviewers with updated job aids/reviewer guides to support scientific reviewers and to enhance the overall efficiency of the science-based decision-making process.

The center will aim to develop further information for the public and regulated industry about how the “appropriate for the protection of the public health” standard is evaluated to aid in product review.

OBJECTIVE 2.2

Ensure Clear Communication and Transparency Related to Tobacco Product Review Processes and Marketing Decisions

To ensure clear communication and transparency related to tobacco product review, CTP will engage with external stakeholders and provide further information to assist applicants in preparing and submitting premarket tobacco product applications. CTP will use a variety of strategies to engage with stakeholders, including holding Tobacco Products Scientific Advisory Committee (TPSAC) meetings, as well as other public meetings and workshops, attending and participating in scientific meetings and conferences, and convening webinars and listening sessions. These public forums provide an opportunity for CTP to learn from all stakeholder perspectives, share information and current thinking, facilitate discussion, and answer questions on the review and decision-making process. CTP will also continue to respond to meeting requests to discuss the design and implementation of studies intended to support premarket tobacco product applications.



In addition to actively engaging with stakeholders, CTP will develop and post resources on the CTP website to communicate scientific issues and practices. Strategies include the following:



Continue to develop guidance documents for industry and online resources (e.g., fact sheets, videos) to support preparation and submission of premarket tobacco product applications.



Resume posting scientific policy memos and reviewer guides (i.e., documents developed to assist FDA reviewers with the evaluation of new tobacco product applications), as appropriate, so that applicants have greater insight into the regulatory review process.



Continue to provide regular updates about tobacco product decisions and progress to the public through multiple channels, including press releases, emails, website updates, and social media outreach, as well as development of a searchable public database of all tobacco products that have an FDA marketing order to further achieve transparency.

OBJECTIVE 2.3 **Utilize the Best Available Science to Inform Decision-Making**

CTP will continue to take a comprehensive approach to ensuring that the most robust and reliable science informs regulatory and product review decision-making. A key focus will be ensuring that the center is funding and conducting timely, relevant, and high-impact research—in collaboration with other FDA centers and federal research partners, including the National Institutes of Health (NIH)—focused on filling critical research gaps related to the review of traditional and novel tobacco products. To help achieve this goal, the center plans to regularly review and update its research priorities, as appropriate, and communicate these priorities to the research community. The priorities will include those related to health equity considerations. In addition, the center plans to continue evaluating the reach and utility of the tobacco regulatory science research program through examining the influence of CTP-funded

research on key regulatory documents and implementing competitive funding cycles for in-house research.

Further, as introduced in Objective 2.2, CTP plans to increase its use of TPSAC to obtain input on scientific issues, with a goal of bringing critical scientific topics to the Committee at least once per year. This may include scientific issues relevant to specific product applications or those that are cross-cutting, such as how the center evaluates toxicological and behavioral evidence to inform its review decisions.

To ensure that the center's scientific staff are as informed as possible, CTP will continue to engage at public forums as well as conferences, symposia, and other convenings, as well as publish scientific papers in peer-reviewed literature, to advance the dialogue around emerging scientific topics.

GOAL 3 : **Strengthen Compliance of Regulated Industry Utilizing All Available Tools, Including Robust Enforcement Actions**



Protecting the public from violative products is fundamental to CTP's mission and requires vigilant surveillance and rigorous enforcement. CTP will continue to strive for maximum voluntary compliance through education and clear communication regarding regulatory requirements. CTP will continue to harness market intelligence and timely collected data and evidence to adeptly adjust enforcement priorities to respond to epidemiological trends and changes in the tobacco marketplace. To ensure that CTP's enforcement efforts are impactful, the center will continue to leverage strong partnerships with federal enforcement partners.

OBJECTIVE 3.1 **Enhance Educational Resources That Facilitate Voluntary Compliance by Regulated Industry**

A key component of CTP's compliance efforts will be to encourage industry's voluntary compliance with tobacco laws and regulations, to proactively prevent violations of the law requiring enforcement action.

The education and engagement of regulated industry are vital to success in obtaining compliance and will require clear, consistent

OUTCOMES

- **Violative Tobacco Products, Particularly Those That Appeal to Youth, Are Not in the Marketplace**
- **Regulated Industry Is Educated on How to Be Compliant With the Law**

education of the regulatory requirements and messaging regarding tobacco laws and regulations. It will also necessitate outreach

to industry trade groups and other industry stakeholders to promote awareness and understanding of the center's enforcement practices and priorities. CTP will continue to develop instructional materials and information, including webinars, web content, and guidance documents, to explain the regulatory requirements, priorities, deadlines, and strategies for

OBJECTIVE 3.2
Pursue Timely and Impactful Compliance and Enforcement Strategies That Adapt to the Evolving Marketplace

CTP remains firmly committed to aggressive enforcement of the law and pursuing enforcement actions against manufacturers, distributors, importers, and retailers for

CTP will continue to identify those manufacturers, distributors, retailers, and importers who fail to voluntarily comply with the law using inspections, online surveillance, and investigations to develop evidence of violations to support enforcement actions.

complying with the laws and regulations. CTP will continue to provide the industry with ways to access answers to questions on compliance, including through its Office of Small Business Assistance.

While remaining agile to take enforcement actions for non-compliance as needed, CTP will strive to ensure transparency regarding enforcement priorities. For example, CTP will work to develop a digital strategy for publicizing certain tobacco enforcement information, which may include maintaining a webpage detailing CTP's compliance and enforcement activities for unauthorized tobacco products. CTP will also help facilitate public presentation of those tobacco products that are legal to sell through the development of a searchable public database of all tobacco products that have an FDA marketing order. CTP also intends to create infographics and other straightforward visualizations that explain the compliance and enforcement processes from product authorization to enforcement actions.

violating the law. CTP will use all available resources, tools, and remedies, as appropriate, to take action when evidence of violations of the law is obtained. CTP will continue to identify those manufacturers, distributors, retailers, and importers who fail to voluntarily comply with the law using inspections, online surveillance, and investigations to develop evidence of violations to support enforcement actions. The tobacco landscape continues to evolve. It is crucial that CTP remain vigilant and agile to be able to adapt to the continually and rapidly changing marketplace. This includes following up with firms that do not comply with the law and taking escalating actions, as appropriate.

To empower CTP to maximize the effectiveness of its enforcement efforts to protect public health, the center intends to pursue enforcement actions that can be developed and filed quickly, such as continuing to seek civil money penalties and pursue judicial actions, including injunctions when appropriate, as an enforcement tool when manufacturers continue to violate

the law after receiving a warning letter. At the same time, CTP will collaborate across the organization to prioritize regulations and guidance documents listed in the center's annual agenda to advance tobacco enforcement goals. Further, the center will work with FDA colleagues outside of CTP and at other federal agencies on further strategies and options to remove unauthorized tobacco products from the marketplace.

CTP's agility and effectiveness in enforcement will also be enhanced by data modernization and integration activities to facilitate information sharing and management, including cloud storage, with an aim toward formatting data for utility in enforcement purposes. CTP will further enhance its capabilities in analyzing tobacco surveillance data to conduct landscape analyses to continue to inform its data-driven decision-making. In addition, as the tobacco landscape evolves, CTP will consider whether statutory changes and/or new regulations are needed to aid in enforcing the law. If it determines so, CTP, in coordination with relevant FDA and HHS offices and the administration, will seek the needed authorities from Congress and work with colleagues in FDA to develop the necessary regulations.

OBJECTIVE 3.3 **Collaborate With Other Federal and State Agencies on Compliance and Enforcement Strategies**

CTP has well-established relationships with other agencies to advance effective compliance and enforcement collaboration, and in this area, plans to continue several established activities and to advance specific new initiatives to enhance our overall capability. This includes strategizing further and exploring additional opportunities for streamlining activities



within FDA and with external enforcement partners such as the Department of Justice to optimize our approaches. We will also explore charting enforcement actions that may deliver greater efficacy and impact against regulated companies and tobacco products that are in violation of the law while optimizing use of resources in mutual information sharing.

Similarly, the center will continue to coordinate with such partners as the Bureau of Alcohol, Tobacco, Firearms, and Explosives and the Federal Trade Commission to maximize opportunities to share information and leverage resources to support enforcement actions. Further, we will leverage and continue our work with the Department of Homeland Security's U.S. Customs and Border Protection and United States Postal Service to enhance tobacco import screening, surveillance, and enforcement to better prevent violative tobacco products from entering the United States.

GOAL 4: Enhance Knowledge and Understanding of the Risks Associated With Tobacco Product Use



Education is fundamental to achieving CTP's vision of a future free of tobacco-related illness. CTP will continue to pursue a broad range of timely, clear, and evidence-based health communication strategies to promote public awareness of the risks associated with tobacco products—including efforts to prevent youth from initiating smoking, encourage cessation, and inform adult smokers about the relative risks of tobacco products. To further empower the public to better understand how and why tobacco is regulated, CTP will remain committed to broadly disseminating timely, accurate, and accessible regulatory information.

OBJECTIVE 4.1 **Educate Youth About the Risks of Tobacco Product Use**

To protect those living in the United States from tobacco-related disease and death, CTP provides evidence-based information to young people about the harms of tobacco product use. Educating young people about the dangers of using tobacco products is a critical part of FDA's public health mission. CTP has implemented and will continue to provide targeted media campaigns, educational programs, and online platforms

OUTCOMES

- **The Public Receives Timely and Clear Health Communication and Education**
- **The Public Receives Evidence-Based Health Communication and Education**

aimed to prevent and reduce tobacco product initiation by young people. CTP plans to continue to prevent tobacco product initiation by young people through

the evidence-based “The Real Cost” public education campaign, which has effectively prevented teens from initiating smoking nationally.

Building on this success, CTP expanded “The Real Cost” campaign to educate young people about the harms of e-cigarette use and will continue to build a comprehensive approach to reduce use of e-cigarettes by young people, including through media campaign interventions. CTP will continue to use a data-driven approach by conducting foundational, formative, and evaluation research to inform its public education efforts and the field of health communication. In addition, CTP will continue to enhance both its online [Tobacco Education Resource Library](#) and its [Vaping Prevention and Education Resource Center](#), which offer free youth tobacco prevention materials and resources for public health practitioners, health care providers, school nurses, educators, parents, and more. CTP will make additional resources available to order or download and include print materials, web content, and social media content.

OBJECTIVE 4.2 **Educate People Who Use Tobacco Products About the Benefits of Cessation**

To increase awareness and provide information about the benefits of cessation among people who use tobacco, CTP will continue to develop public education messaging that utilizes diverse methods to reach a wide range of people who use tobacco. Building on the “Every Try Counts” tobacco cessation campaign, CTP will continue to disseminate educational materials through its online [Tobacco Education Resource Library](#) to promote cessation among adults who smoke. CTP will continue to leverage collaborations with public health stakeholders and other federal

agencies, including the National Cancer Institute, to expand digital cessation education resources and work to significantly reduce tobacco-related disease and death, including from cancer. CTP will support government-wide efforts to help people stop using tobacco products.

OBJECTIVE 4.3 **Educate Adults Who Smoke About the Relative Risks of Tobacco Products**

CTP will work to increase awareness and provide information about the relative risks of tobacco products to adults who smoke using a data-driven approach to maximize impact on the intended audience and to minimize impact on unintended audiences (e.g., youth).

CTP will continue to conduct foundational and formative research about understanding of the continuum of risk, relative risk perceptions, and modified risk products among adults who use tobacco and other population groups to inform potential educational efforts. For example, CTP has initiated multiple research studies that examine tobacco product risk perceptions and misperceptions held by adults who smoke as well as their tobacco use behaviors.

In addition to this formative work within the center, CTP will continue to leverage extramural research and partnerships to inform evidence-based efforts to educate stakeholders and adults who use tobacco products about the relative risk of these products. For example, in August 2023 NIH published a Notice of Funding Opportunity (NOFO) reflecting the partnership between NIH and CTP to foster tobacco regulatory research to better understand the impact that messaging about the continuum of risk for tobacco products may have on various segments of the U.S. population. Findings from the collective efforts will inform potential future education efforts about relative risk, including tailored strategies for populations that experience tobacco-related health disparities.

GOAL 5: **Advance Operational Excellence**



CTP's ability to meet its public health mission is dependent on its strength as an organization. The complexities of tobacco regulation require an expert, well-supported workforce that is empowered to succeed. CTP recognizes diversity of expertise, experience, and identity as intrinsically valuable and remains committed to fostering a culture of respect and inclusion in the workplace. CTP will remain committed to improving work processes to ensure that staff have the resources they need to advance the center's mission.

OBJECTIVE 5.1 **Support and Further Develop a Highly Qualified, Inclusive, and High-Performing Workforce**

CTP's people are the core of the center, and a strong, supported workforce is crucial to effectively achieving its mission. As such, CTP will champion meaningful initiatives to enhance employee retention and engagement and to grow the center's workforce while building and maintaining a

OUTCOMES

- **A Talented, Diverse, and Engaged Workforce Is Attracted and Retained**
- **Business Operations Are Efficient and Effective in Supporting Programmatic Goals**

positive workplace culture and focusing on the key organizational values of diversity, equity, inclusion, and accessibility (DEIA).

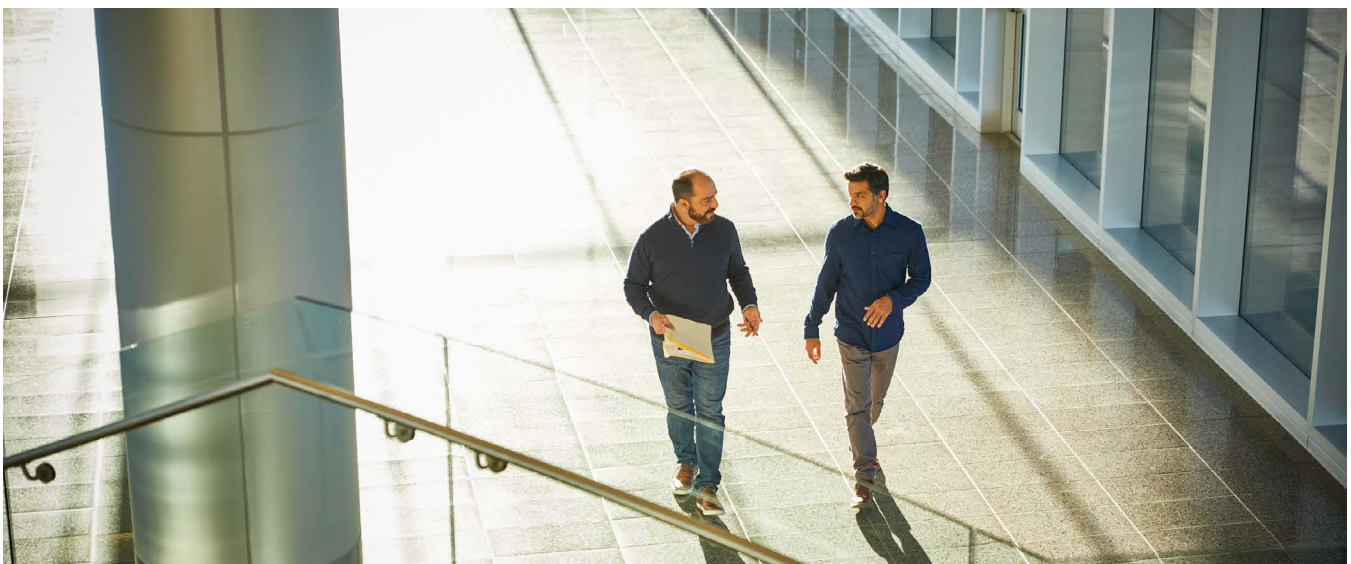
Retention: To sustain and support its highly skilled and diverse workforce in a challenging, competitive environment, CTP must ensure it demonstrates to employees that they are valued and recognizes their vital contributions to advancing CTP's

Engagement: In fulfilling our continued commitment to build and maintain a cohesive, resilient, and positive workplace culture, CTP will focus on approaches to advance collaboration, empowerment, engagement, and belonging. This includes

CTP will also continue to ensure mechanisms are available to foster empowerment and belonging and to encourage open communication and collaboration across the organization—informally and formally, from the team level to the office level.

mission, goals, and objectives. The center will place greater emphasis on workload management, career development, succession planning, and employee compensation and recognition programs. For example, CTP will support growing talent from within the organization to benefit from institutional knowledge, experience, and expertise. Further, CTP will prioritize training and development opportunities to ensure staff are set up for success, experience job satisfaction, and further develop their careers within the organization.

regularly seeking, considering, and using employee feedback to enhance the workplace experience, including through employee surveys. CTP will use the results from key questions to gauge progress. CTP will also continue to ensure mechanisms are available to foster empowerment and belonging and to encourage open communication and collaboration across the organization—informally and formally, from the team level to the office level. The center will adopt relevant best practices to ensure meaningful leadership actions are taken on a regular basis, conduct additional analyses



to pinpoint possible issues, and take actions each year that continue to push toward positive results. This includes leveraging and further implementing strategies and activities identified by cross-agency teams as well as management aimed at increasing and enhancing employee engagement at all levels of the organization.

Recruiting and Hiring: CTP must continually bring on new staff to grow and ultimately maintain our capacity and capabilities. New staff also bring new ideas, energy, and diversity into the organization. To achieve this, CTP will use targeted, effective outreach and recruitment strategies to attract diverse and highly qualified candidates from within and outside the government, and ensure efficient processes are in place to hire additional staff. This includes partnering with human resources experts and hiring managers, both within FDA and elsewhere in the federal government, to increase the center's hiring pace, with the goal of increasing the size of the CTP workforce.

Diversity, Equity, Inclusion, and Accessibility (DEIA): CTP recognizes that advancing its mission depends on

building and maintaining a safe and fair work environment that ensures equal employment opportunity, values diversity and inclusion, and ensures all voices are heard and contributions are valued. CTP is committed to advancing a robust workforce DEIA program that will ensure center leadership demonstrates commitment, communications, and actions that cultivate and promote an inclusive culture as well as build and maintain a diverse workforce.

OBJECTIVE 5.2

Ensure the Most Efficient and Effective Use of Financial Resources

CTP recognizes the importance of accountability and responsible stewardship of financial resources through strategic and effective resource management. This requires agility and acumen in setting budgets and carefully aligning resources to CTP priorities, reflecting an optimized use of funds to achieve its public health goals.

The center will continue to facilitate effective resource planning in the short and long term, leveraging resource planning capabilities along with its unique user-fee structure to enhance effectiveness



and strategic alignment of CTP's use of resources. CTP will continue to seek needed resources and work toward a fair and equitable way to collect user fees for all regulated products.

To minimize disruptions to the center's workstreams in a constrained budget environment, CTP will be vigilant in efforts to identify and assess potential risks and to implement strategies to mitigate or manage risks, while adhering to legal, regulatory, and ethical standards. CTP will promote a culture of compliance and accountability through transparency on budget decisions and tradeoffs, and strong acquisition and grant management. To this end, CTP will seek opportunities to educate staff and provide information on internal controls and administrative management.

OBJECTIVE 5.3 **Continually Advance Operational Enhancements**

CTP is committed to continually advancing operational enhancements and fostering initiatives that encourage innovation, collaboration, and knowledge sharing to drive proactive and thoughtful problem solving. This includes continuing to build and maintain strong internal relationships with partners, customers, and service providers to better deliver on operational needs. To promote collaboration and resolution for mutual benefit, CTP will develop and document more robust roles and responsibilities that advance productive working relationships and mutual accountability; this will, in turn, assist in ensuring that the CTP workforce is to obtain the information and support it needs. In addition, through enhanced efforts to proactively approach change management, CTP will place emphasis on communicating

the rationale and potential benefits for proposed changes and provide resources to help employees adapt and adopt them.

CTP also aims to optimize business processes and service-oriented solutions, focusing on strategic IT development and operational optimization. By facilitating IT development and enhancements that produce integrated IT and data platforms while optimizing IT system efficiency, the center will reduce redundancy and costs and, relatedly, ensure data protection and privacy. To ensure successful implementation of these enhancements, CTP will seek opportunities for cross-agency collaboration and alignment with the shared FDA IT ecosystem, and further refine IT governance structures to provide greater oversight, assess mission and business value, and manage risks effectively. Furthermore, CTP intends to improve our capabilities to track and evaluate projects throughout the life cycle and measure the performance of our IT portfolio in meeting mission needs. Leveraging strong IT infrastructure and governance, CTP will continually refine operations through enhancement and implementation of technology and data-supported solutions.

The center will also prioritize maintaining and advancing efficient and effective management operations by providing clear administrative guidance and procedures, continually improving processes, and fostering accountability. This will include continuing to develop and implement more formalized standard operating procedure documentation for key operational processes and provide associated training to ensure knowledge management and transfer.

APPENDICES

A1. Summary of Public Oral and Written Comments From the Aug. 22, 2023, Public Listening Session for Developing FDA's Center for Tobacco Products' Strategic Plan and the Public Docket

On Aug. 22, 2023, FDA's Center for Tobacco Products held a 6-hour virtual public listening session to hear stakeholder feedback on the proposed goal areas and cross-cutting themes for the draft strategic plan. [CTP also established a docket \(FDA-2023-N-2873\)](#) to receive written comments which was open from July 24, 2023, to Aug. 29, 2023.



2,436

COMMENTS WERE SUBMITTED TO THE DOCKET IN TOTAL. OF THESE:

1,129

Were identified as unique (125 substantive and 1,004 other unique comments).

1,299

Were form letter copies from two campaigns.

8

Were duplicate comments.



76

Requests to speak were yielded from participants who were provided an opportunity to register to make a spoken comment during the meeting.

4

Minutes were given to all who requested an opportunity to speak.

59

Of the registered speakers ultimately were present to deliver their comments.



841

REGISTERED ATTENDEES IN TOTAL, OF THESE:

76

Requested to comment

765

Listen-only attendees

551

Stakeholders in total were present during all or parts of the meeting (excluding event support staff and moderators).

Comments were submitted by a breadth of stakeholder groups, including national/state/local public health professionals, academics/researchers, community and/or faith-based organizations, tobacco industry representatives, and the general public. Many comments covered more than one goal or theme area, and a summary of the topical areas covered are as follows:



GOAL 1: Topics included communicating a policy agenda, advancing rulemakings for product standards, and pursuing additional statutory or regulatory authorities.



GOAL 2: Topics included simplifying and clarifying the application process and improving communication with stakeholders.



GOAL 3: Topics included enforcing product standards, distribution and market availability of unauthorized products, underage access to products, foreign importation of tobacco products, and communications between FDA and retailers, industry, and other law enforcement entities.



GOAL 4: Topics included science-based communications, youth education, misinformation about the health effects of nicotine and tobacco products, the continuum of risk, and reduced harm alternatives.



GOAL 5: Topics included prioritizing DEIA recruitment practices, embedding stakeholder engagement in organizational structure, and using programmatic metrics to measure success.

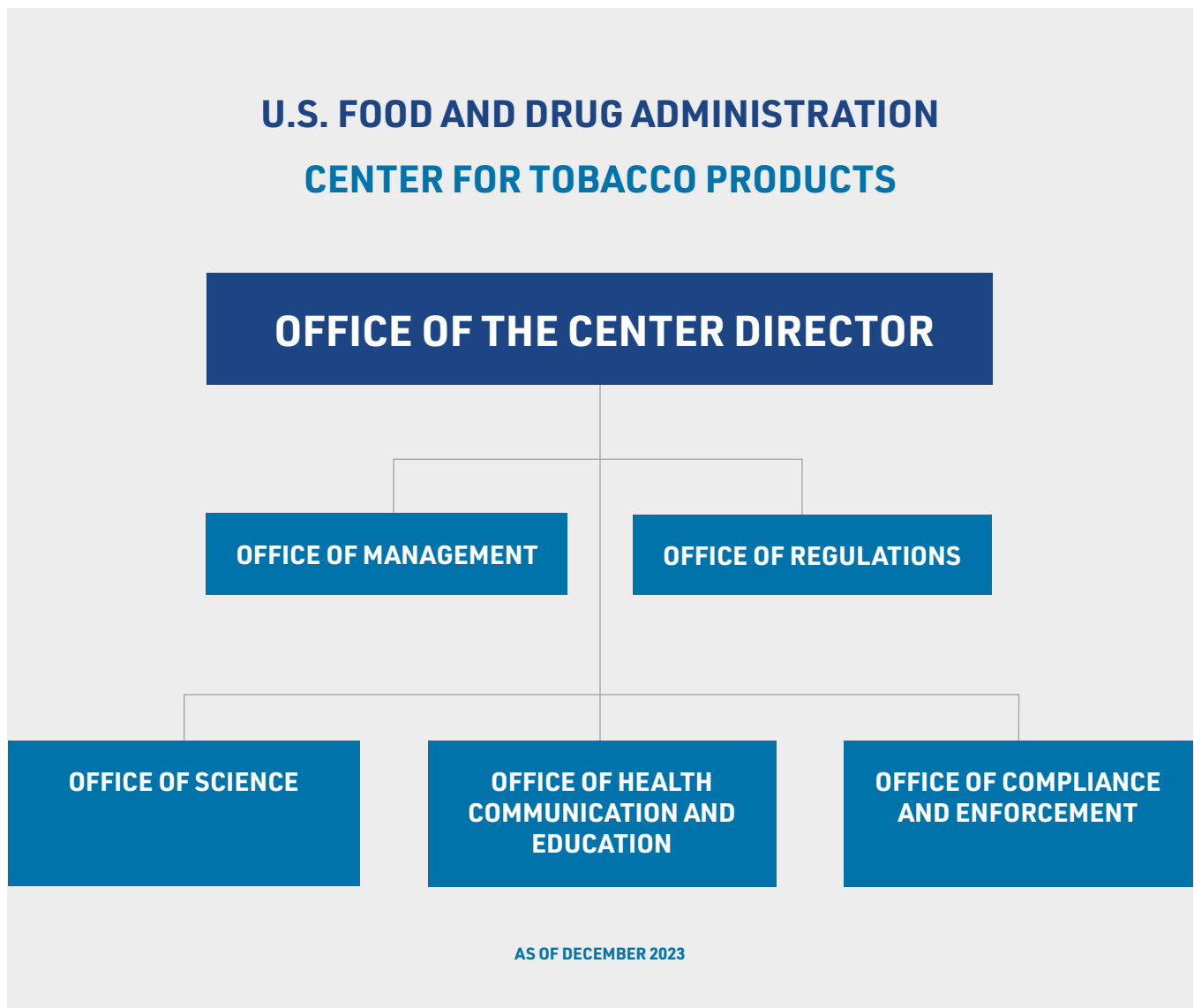
A number of comments also addressed the proposed cross-cutting themes, including but not limited to the following:

- **Science:** Topics included upholding rigorous standards for evidence-based decision-making and policy development.
- **Health equity:** Topics included considering the impact of regulation on minority communities, some recommending guidance rather than rulemaking to avert criminal penalties in the tobacco marketplace that might have an adverse impact on communities of color, and many expressed concerns regarding the pending final rule banning the use of menthol in cigarettes.
- **Stakeholder engagement:** Topics included recommendations that CTP undertake a broad range of engagement strategies, as related to the use of expert advisory bodies, workshop convenings, and more routinely scheduled public listening sessions.
- **Transparency:** Topics included endorsing the value of transparency in product application data requirements and evaluation criteria, and suggestions related to health communications regarding youth and adult tobacco use, CTP's policy agenda, marketing decisions, enforcement actions, and a public listing of authorized tobacco products.

Of note, there was a large write-in campaign, comprised of over 1,000 comments expressing opposition to animal testing. CTP's research program supports reducing, replacing, and/or refining the use of animal testing in research where adequate and scientifically valid non-animal alternatives can be substituted; accordingly, the center has reduced the use of animal testing in research in recent years. However, CTP recognizes that there are certain

limited instances where it is currently appropriate to use animals in research. In these limited instances, all CTP-funded animal research projects follow policies and regulations set by the Animal Welfare Act and the [Public Health Service Policy on Humane Care and Use of Laboratory Animals](#). Further, CTP-funded researchers must abide by all Institutional Animal Care & Use Committee standards.

A2. Organizational Chart





CENTER FOR TOBACCO PRODUCTS