We are excited to announce the upcoming release of CTP Portal Next Generation (NG) in early 2025. This new platform introduces web forms for Premarket Tobacco Product Application (PMTA) and Substantial Equivalence (SE) submissions while continuing to support other submission types via eSubmitter. CTP Portal NG will provide a more integrated, efficient, and secure solution for document submissions, with web forms for additional submission types being rolled out in phases following the initial launch.

Key Features of CTP Portal NG

The new CTP Portal NG introduces major improvements to the submission process. While the tobacco industry currently relies on multiple tools (such as PDF-editing software and the FDA's eSubmitter Desktop tool), the upgrade to CTP Portal NG will simplify and enhance these processes.

Dynamic Web Forms: PMTA and SE

One of the most significant changes in CTP Portal NG is the introduction of dynamic web-based forms that allow applicants to create, complete, validate, and submit their submission packages directly through the portal. This new process eliminates the need for using multiple tools such as PDF-editing software and the eSubmitter in the preparation of submission packages, providing a streamlined, integrated solution. CTP Portal NG will initially provide web forms for the new PMTA (FDA Form 4057) and SE (FDA Form 3965) applications, as well as their respective amendments (FDA Forms 4057a and 3965a), with web forms for other submission types being released over time.

Key benefits of the new CTP Portal NG web forms process include:

- Instructions and Support: Provides step-by-step instructions, insightful context-sensitive tooltips and support, and an intuitive user-friendly interface that helps guide users through the submission package preparation process.

- Streamlined Data Entry: The form automatically adjusts based on the user's input, showing only the options that are relevant. It also includes tools to help users complete the forms more quickly.

- Integrated Validation: Provides real-time validation to verify the information entered to help reduce errors before submission.

- Improved Efficiency: Simplifies and expedites the PMTA and SE submission package preparation process by removing the need for multiple software tools.

eSubmitter Submission Package Uploads: Other Submission Types

For submission types other than PMTA and SE, such as Abbreviated SE Reports (AS), Harmful and Potentially Harmful Constituents (HC), Tobacco Product Ingredient Listings (TI), and others, the existing process of using the FDA's eSubmitter Desktop tool will continue. These submission types will not be transitioned to web-based forms in CTP Portal NG initially and will continue to have their submission packages prepared in eSubmitter and uploaded through CTP Portal NG.

The following submission types, among others, will continue using eSubmitter:

- Abbreviated SE Report (AS)

- Substantial Equivalence Exemption (EX)

- Tobacco Harmful and Potentially Harmful Constituents (HC)

- Health Document (HD)

- Other Advertising Media (OM)

- Pre-Existing Tobacco Product (PX)

- Requested Document (RD)

- Rotational Warning Plans (RP)

- General Correspondence – OS Meeting Request (TC)

- Tobacco Product Ingredient Listing (TI)

Improvements in the Submission Process for All Types

CTP Portal NG introduces several enhancements, even for submission types that continue to use the eSubmitter tool. These include:

- Unified Account Access: Users who manage or support multiple organizations will now only need one account to access all of them, simplifying login and account management.

- Enhanced Security: Multi-Factor Authentication (MFA) will be introduced, requiring users to authenticate with a one-time code sent via email, SMS, or an authenticator app. This added layer of security will help protect sensitive data.

- New Submission Portal URL: A new URL for CTP Portal NG will be provided, with a redirect from the current portal URL to ensure a smooth transition.

Transition to CTP Portal NG

To ensure a smooth transition, workshops and training sessions will be conducted prior to the rollout of CTP Portal NG. These sessions will help users become familiar with the new features and processes, providing the necessary guidance for a successful implementation.

To support the transition to CTP Portal NG:

- Existing CTP Portal user accounts will be migrated to the new system, and users may be prompted to reset their passwords upon initial login.

- The submission process for non-PMTA and non-SE types remains largely the same, with eSubmitter still being used for submission preparation, but the submission itself will be uploaded via CTP Portal NG.

- Support and guidance will be available from CTP to help users navigate the upgraded portal and its new features.