Change Request for OMB Control No. 0910-0312

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents

October 24, 2024

FDA's Center for Tobacco Products (CTP) plans to launch CTP Portal Next Generation (CTP Portal NG) – an upgraded web portal for transmitting tobacco industry submission packages to the FDA. CTP Portal NG is scheduled to go live on January 17, 2025.

CTP is seeking OMB approval for this nonmaterial/non-substantive change to reflect an upgrade from the current CTP Portal web application to the new CTP Portal NG. This change specifically addresses one aspect of the upgrade, impacting the submission type, Other Advertising Media (OM), for this collection.

CTP Portal NG will streamline the submission process by offering a single login for users across multiple organizations and integrating Multi-Factor Authentication (MFA) for added security.

When launched, CTP Portal NG will:

- Continue to support the impacted submission types created using the eSubmitter Desktop Tool, with submissions delivered via the new CTP Portal NG.
- Simplify user access by consolidating organization accounts under a single login.
- Require a verification code for login as part of MFA security enhancements.

No action will be required from current users of any FDA systems—existing CTP Portal accounts, along with any pending or in-process applications, will be automatically migrated to the new CTP Portal NG, and users may be prompted to reset their passwords upon their first login.

There are no burden adjustments associated with this change request.

Requested OMB approval date: December 17, 2024.