

# PRE-EXISTING TOBACCO PRODUCTS: UPDATE TO TERM

CENTER FOR TOBACCO PRODUCTS

*Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.*

# VOLUNTARY STANDALONE PX PROGRAM: UPDATES



- On August 19, 2022, the term Grandfathered (GF) tobacco product was changed to Pre-Existing (PX) tobacco product. This change does not affect submissions assigned a “GF” Submission Tracking Number (STN). STNs will now start with the prefix of PX.
- A pre-existing tobacco product has the same definition as a grandfathered tobacco product.
- The standalone voluntary pre-existing review program processes remain the same.

- CTP's commitment to diversity, equity, inclusion, and accessibility.
  - The term “grandfathered” when used to describe someone or something exempt from a new law or regulation has its roots in 19th century racist voting laws.
  - The updated terminology is noted in the Premarket Tobacco Product Application (PMTA) and Substantial Equivalence (SE) final rules. The term “grandfathered tobacco product” was changed to “pre-existing tobacco product” under the rules because it more appropriately describes these products, by using the more precise “pre-existing” in place of “grandfathered.”

# VOLUNTARY STANDALONE PX PROGRAM: DATABASE CHANGES



- As of August 19, 2022, the terminology has been updated in the eSubmitter and CTP Electronic Submission applications. The system updates are limited to terminology changes and users will not encounter major changes. In both systems, “grandfathered” will no longer be a selectable option in menus and will be replaced with the “pre-existing tobacco product” terminology.
- CTP’s standalone Pre-Existing Tobacco Product Determinations database will continue to show GF STNs and new PX STNs. Products can be searched under their originally assigned GF STNs.

# VOLUNTARY STANDALONE PX PROGRAM: THINGS TO REMEMBER



- GF STNs will not be retroactively changed to PX STNs.
- Firms do not need to contact CTP to change or update STNs due to the terminology change.
- Pending or completed submissions do not need to be resubmitted or amended due to the terminology update.
- Applicants with a pending or previously authorized Substantial Equivalence (SE) Report that references a GF product are not required to take any additional action based on this terminology change.
- The process for submitting Voluntary Standalone PX reviews remains the same.

# VOLUNTARY STANDALONE PX PROGRAM: PENDING FUTURE UPDATES



- CTP also plans to update any guidance documents that previously included the term “grandfathered tobacco product.” The Center will announce the availability of the revised final guidance for industry, collectively entitled, “Pre-Existing Tobacco Product Guidance Documents”, via the Federal Register in the future.

# VOLUNTARY STANDALONE PX PROGRAM: CONTACT CHANGES



- The email address for the pre-existing tobacco product determination program has been updated to [CTP-PreExisting@fda.hhs.gov](mailto:CTP-PreExisting@fda.hhs.gov)
  - If you have a question about pre-existing tobacco products, please send an email to [CTP-PreExisting@fda.hhs.gov](mailto:CTP-PreExisting@fda.hhs.gov)
  - Additional pre-existing tobacco product program resources are available online at <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/pre-existing-tobacco-products>