

THE FOOD AND DRUG ADMINISTRATION (FDA) PART TWO: SUBSTANTIAL EQUIVALENCE (SE): REVIEWING PREDICATE TOBACCO PRODUCT ELIGIBILITY

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The FDA logo, consisting of the letters "FDA" in white on a blue square background.

AGENDA:

Presentation Overview

1. Types of Reviews for Proposed SE Predicate Products
2. Overview of FDA Form 3965 & Form 3965b
3. Certification Statement of Affirmation



TYPES OF REVIEWS FOR PROPOSED SE PREDICATE PRODUCTS

TYPES OF REVIEWS FOR PROPOSED PRE-EXISTING PREDICATES: CROSS-REFERENCE AND FULL REVIEWS



- **Cross Reference to Pre-Existing Product Determinations:**

- CTP will verify cross-references to CTP's previous determinations of pre-existing tobacco products. This includes information referencing the pre-existing STN which may have either a GF prefix (pre-existing determinations made prior to August 2022) or a PX prefix (pre-existing determinations made after August 2022).
 - For more information on FDA's voluntary standalone pre-existing tobacco determinations, please view FDA's three-part webinar series on CTP's pre-existing Tobacco Product Determination Program.

- **Full predicate tobacco product review:**

- Full predicate reviews are conducted when the applicant identifies a predicate tobacco product in the SE Report that does not have a previously assigned PX or GF STN or a pre-existing determination made by FDA.

OVERVIEW OF FDA FORM 3965 & FORM 3965b

OVERVIEW OF FDA FORM 3965



- As of July 6, 2025, applicants must use the most recent version of the forms listed below in their SE Report submissions. If applicants do not complete the forms properly, FDA intends to refuse to accept the application or may not review information submitted as amendments. SE correspondence must be submitted electronically. Forms FDA 3965 and 3965a can be completed within CTP Portal NextGen.
 - Form FDA 3965 – Tobacco Substantial Equivalence Report Submission
 - Form FDA 3965a – Tobacco Substantial Equivalence Report Amendment and General Correspondence Submission (formerly Form FDA 3964)
 - Form FDA 3965b – Tobacco Substantial Equivalence Report Unique Identifying Information for New Tobacco Product Spreadsheet
- These forms are available in CTP Portal NextGen or can be downloaded on FDA's website: <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/substantial-equivalence>.

REQUIRED PREDICATE PRODUCT INFORMATION FORMS

FDA 3965 & 3965b



Form FDA 3965 Section III

- Type of Predicate: Whether the predicate product previously determined or is claimed to be pre-SE in a previous SE
- If the predicate product was previously determined or is claimed to be pre-existing:
- Evidence of Commercial Marketing in the U.S. as of February 15, 2007
- If the SE Report cross-references a product previously determined to be predicate eligible under the voluntary PX program, cross-referenced information including the STN.

Form FDA 3965b

Requires information that uniquely identifies the new tobacco product and the predicate tobacco product for comparison in an SE Report. Examples of identifying characteristics include:

- Package type
- Quantity
- Length
- Diameter
- Flavor

CERTIFICATION STATEMENT OF AFFIRMATION

CERTIFICATION STATEMENT OF AFFIRMATION



- If the identified predicate product is a pre-existing tobacco product, the SE Report must include a statement such as “I (insert name and position title of responsible official), confirm that the predicate tobacco product associated with this submission, (insert name of predicate tobacco product), was commercially marketed (other than exclusively for test marketing) in the United States as of February 15, 2007.”

RESOURCES:



PRE-EXISTING TOBACCO PRODUCT QUESTIONS

Email: CTP-pre-existing@fda.hhs.gov

PRE-EXISTING TOBACCO PRODUCT WEBSITE

<https://www.fda.gov/tobaccoproducts/labeling/tobaccoproductreviewevaluation/ucm304380.htm>

SECTION 910 of the FD&C ACT

https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm262073.htm#910_a_1_B

CTP PORTAL

<https://ctpportal.fda.gov/ctpportal/login.jsp>

FDA ESUBMITTER

<https://www.fda.gov/ForIndustry/FDAeSubmitter/ucm189469.htm>

FDA's DOCUMENT CONTROL CENTER ADDRESS

<https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp>

PRE-MARKET TOBACCO APPLICATION FINAL RULE

<https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications>

PRE-EXISTING GUIDANCE

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/establishing-tobacco-product-was-commercially-marketed-united-states-february-15-2007-revised>

SE GUIDANCE

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/demonstrating-substantial-equivalence-new-tobacco-product-responses-frequently-asked-questions>

SEARCHABLE TOBACCO PRODUCTS DATABASE

<https://www.accessdata.fda.gov/scripts/searchtobacco/>

SUBSTANTIAL EQUIVALENCE PROCESS, RULES, AND GUIDANCE

<https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/substantial-equivalence>

EXEMPTION FROM SUBSTANTIAL EQUIVALENCE

<https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/exemption-substantial-equivalence>

THANK YOU!

FDA



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ADMINISTRATION

Center For Tobacco Products