

PRE-EXISTING TOBACCO PRODUCT DETERMINATION-PROGRAM WEBINAR SERIES

PART 1 OF 3:

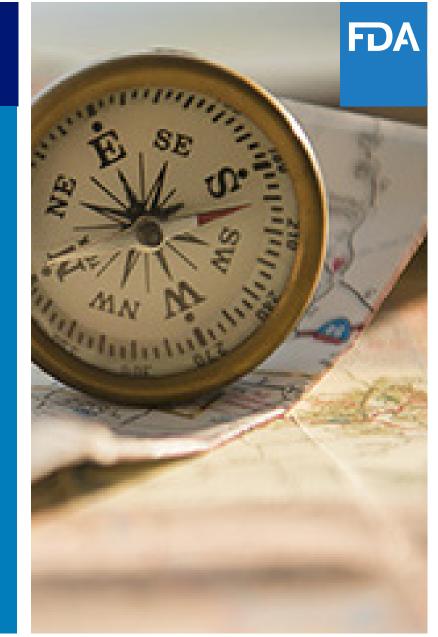
WHAT IS A PRE-EXISTING -TOBACCO PRODUCT (PTP)?

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

AGENDA

Presentation Overview

- 1. New and Pre-Existing Tobacco products
- 2. Overview of The Pre-Existing Tobacco Product (PTP) Program
- 3. Pre-Existing Tobacco Products Serving as a predicate
- 4. Additional Resources





COMPARING NEW AND PRE-EXISTING TOBACCO PRODUCTS

A New Tobacco Product is:

 Any tobacco product (including those products in test markets) that was <u>not</u> commercially marketed in the United States as of February 15, 2007.

A Pre-Existing Tobacco Product is:

 Any tobacco product (including those products in test markets) that was commercially marketed in the United States as of February 15, 2007. FDA interprets "as of February 15, 2007" to mean on February 15, 2007.*

*Guidance for Industry: Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007 (Revised), October 2023

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OVERVIEW OF THE PRE-EXISTING TOBACCO PRODUCT (PTP) PROGRAM

TERMINOLOGY UPDATE: GRANDFATHER TO PRE-EXISTING

- On August 19, 2022, CTP updated its terminology. Previously, a "pre-existing tobacco product (PTP)" was termed "grandfathered tobacco product (GF)."
- Products currently submitted for status determination under the Pre-Existing Program are assigned a submission tracking number (STN) that begins with "PX." Under the previous terminology, FDA assigned a GF identification number to products submitted for voluntary status determination. The updated terminology does not affect the status of those products which retain their GF submission number.
- For more information on the terminology update, please see the FDA webinar "<u>Pre-Existing Tobacco</u> <u>Products: Updates to Term</u>."

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VOLUNTARY PRE-EXISTING TOBACCO PRODUCT (PTP) DETERMINATION PROGRAM

 Firms may submit written requests for FDA to determine whether a tobacco product is pre-existing including evidence of commercial marketing.

Submitting requests under the Pre-Existing Tobacco Product (PTP) Program is voluntary.

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WHAT IS A PRE-EXISTING TOBACCO PRODUCT?



- A Pre-Existing tobacco product is any tobacco product (including those products in test markets) that was commercially marketed in the United States as of February 15, 2007.
- Pre-Existing tobacco products are not new tobacco products. Pre-Existing tobacco products do not require FDA prior marketing authorization to be legally marketed in the United States.

WHAT DOES NOT QUALIFY FOR PRE-EXISTING TOBACCO STATUS?

- Modified tobacco products
- Pre-Existing status determinations are made for finished, regulated tobacco products.
- Tobacco products commercially marketed after February 15, 2007, but not as of the Pre-Existing date.

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WHAT IS COMMERCIALLY MARKETED?



- "Commercially marketed" is defined as "selling or offering for sale a tobacco product in the United States to consumers or to any person for the eventual purchase by consumers in the United States"*.
- Tobacco products that were commercially marketed in the United States solely in test markets as of February 15, 2007, may qualify as a Pre-Existing tobacco product, but not as a predicate product.

*21 CFR § 1100.202



PRE-EXISTING TOBACCO PRODUCTS SERVING AS A PREDICATE

WHAT IS A PREDICATE PRODUCT?

A predicate product may be either:

- A tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; or
- A tobacco product that FDA has previously determined to be substantially equivalent and in compliance with the requirements of the FD&C Act.*

A Substantial Equivalence Report must compare a new tobacco product to a predicate tobacco product.

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

PRE-EXISTING PRODUCT MARKETED SOLELY FOR TEST MARKETING MAY NOT SERVE AS A PREDICATE

- A pre-existing tobacco product is any tobacco product (including those products in test markets) that was commercially marketed in the United States as of February 15, 2007
- A predicate product is a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007;
- A pre-existing product commercially marketed solely in a test market as of February 15, 2007, is not eligible to serve as a predicate product in a Substantial Equivalence (SE) report.

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ADDITIONAL RESOURCES

SEARCHABLE TOBACCO PRODUCTS DATABASE

FDA

Located at: www.fda.gov/searchtobacco

Searchable Tobacco Products Database

This database provides entries for tobacco products that may be legally marketed because they are 1) new tobacco products authorized through one of <u>three pathways to market</u>, 2) established through a voluntary determination program as <u>pre-existing tobacco products</u> (commercially marketed as of Feb. 15, 2007), or 3) <u>provisional tobacco products that were removed from review</u>. For more information on database terminology and Q&A, visit <u>Searchable Tobacco Products Database - Additional Information</u>.

FDA also maintains a printable flyer of authorized e-cigarettes.

No tobacco product is safe, and it is illegal to sell tobacco products to anyone under 21. Products in this database may be the subject of agency action for other reasons.

Download All Records 📥

Search the Database

Search Company, Product Name, STN, MRTP, Additional Information		
Category	Sub-Category	Submission Type - Marketing Authority
Select options *	Select options *	Select options *
Date of Action From	Date of Action To	
mm/dd/yyyy	mm/dd/yyyy	
	Search Q Reset 2	
	ubmission Type - Date of Action Order Letter Decision Summary arketing Authority	Environmental FONSI STN Associated Additional Assessment MRTP Information
Please perform a search to see results.		

RESOURCES



Pre-Existing TOBACCO PRODUCT QUESTIONS

Email: <u>CTP-Preexisting@fda.hhs.gov</u>

Pre-Existing TOBACCO PRODUCT WEBSITE

https://www.fda.gov/tobaccoproducts/labeling/tobaccoproductrevieweval uation/ucm304380.htm

SECTION 910 of the FD&C ACT

https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidan ce/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-productsctp/contact-ctp

PRE-MARKET TOBACCO APPLICATION FINAL RULE

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

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PRE-EXISTING GUIDANCE

https://www.fda.gov/regulatory-information/search-fda-guidancedocuments/establishing-tobacco-product-was-commercially-marketedunited-states-february-15-2007-revised

SE GUIDANCE

https://www.fda.gov/regulatory-information/search-fda-guidancedocuments/demonstrating-substantial-equivalence-new-tobacco-productresponses-frequently-asked-questions

FDA's DOCUMENT CONTROL CENTER ADDRESS

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

STANDALONE Pre-Existing SUBMISSION DATABASE

https://www.accessdata.fda.gov/scripts/ctpgnd/

SUBSTANTIAL EQUIVALENCE PROCESS, RULES, AND GUIDANCE

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

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<u>YouTube</u>

http://www.youtube.com/playlist?list=PLA803FAFDFA860129

Sign Up for Email Updates on Tobacco Products

https://www.fda.gov/tobacco-products/newsroom/sign-email-updates-ctp

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