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.

FDA

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

NEW AND PRE-EXISTING TOBACCO PRODUCTS DEFINED

A New Tobacco Product is:

- Any tobacco product (including those products in test markets) that was **not** 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

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 "Pre-Existing Tobacco Products: Updates to Term."

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.

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.

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.

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

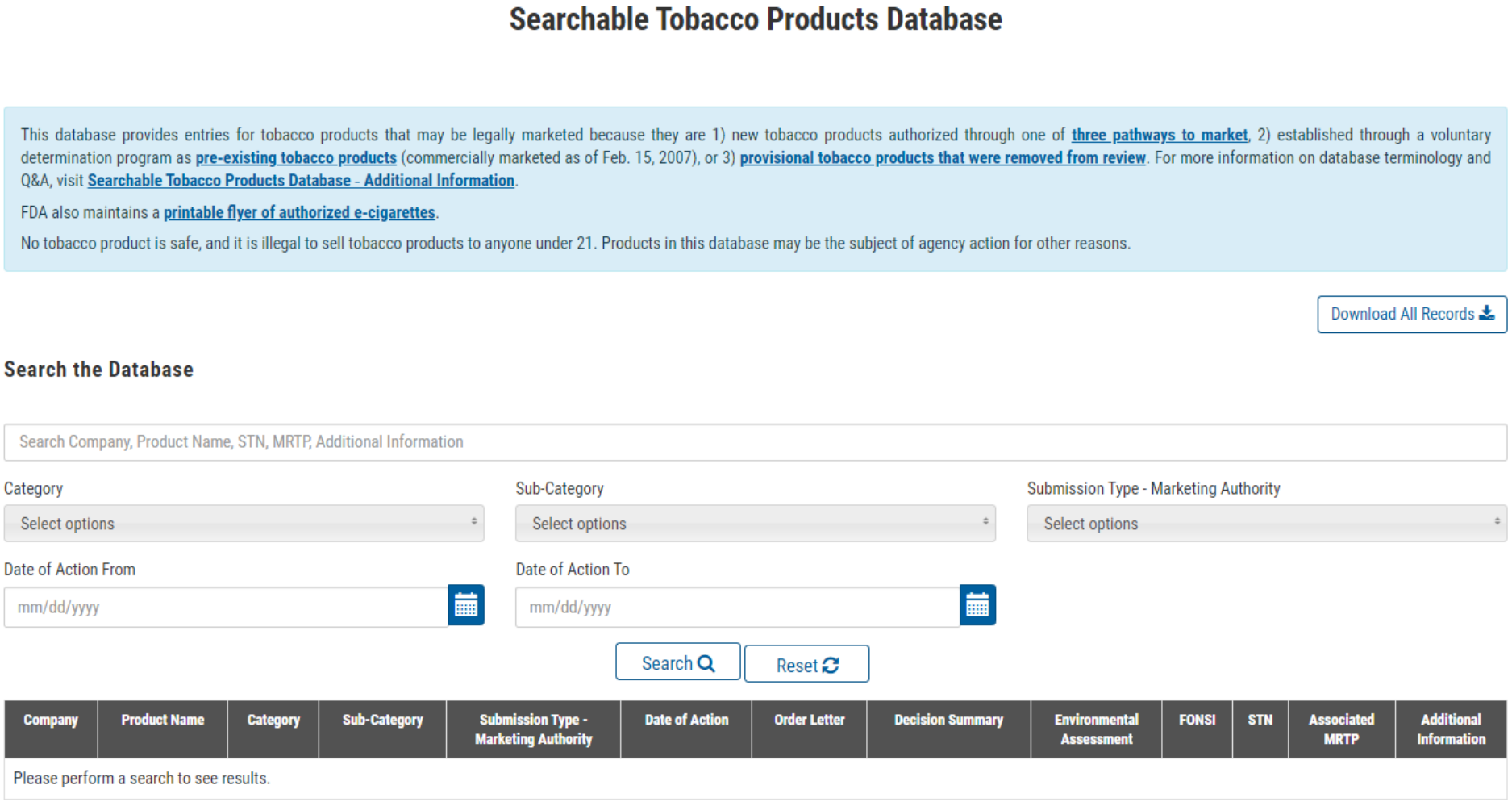
PRE-EXISTING PRODUCT MARKETED SOLELY FOR TEST MARKETING MAY NOT SERVE AS A PREDICATE

- 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.

ADDITIONAL RESOURCES

SEARCHABLE TOBACCO PRODUCTS DATABASE

Located at: www.fda.gov/searchtobacco



RESOURCES

Pre-Existing TOBACCO PRODUCT QUESTIONS
Email: CTP-Preexisting@fda.hhs.gov

Pre-Existing TOBACCO PRODUCT WEBSITE
https://www.fda.gov/tobaccoproducts/labeling/tobaccoproductrevieweveluation/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

FDA's DOCUMENT CONTROL CENTER ADDRESS
https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/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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YouTube

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