PRE-EXISTING TOBACCO PRODUCT DETERMINATION-PROGRAM WEBINAR SERIES

PART 2 OF 3:

PREPARING AND SUBMITTING A STANDALONE PRE-EXISTING SUBMISSION

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AGENDA

Presentation Overview

1. Preparing Voluntary Pre-Existing Tobacco Product Status Determination Requests
    - Submission Components
    - Major Submission Components
    - Submission Checklist
    - Tobacco Product Name
    - Unique Identifiers
    - Commercial Marketing Evidence
    - Linking information
2. Reasons for Requests for Information
3. Additional Resources

PREPARING VOLUNTARY, PRE-EXISTING TOBACCO PRODUCT STATUS DETERMINATION REQUESTS

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.

- FDA Interprets the phrase “as of” February 15, 2007, to mean “on” February 15, 2007.

COMPONENTS OF A SUBMISSION

- A description of the tobacco product, including the name as it was commercially marketed under as of February 15, 2007, and characteristics that uniquely identify it.

- A statement that the product was commercially marketed, in the United States as of February 15, 2007.

    - If the Pre-Existing product is intended to be used as a predicate in the Substantial Equivalence (SE) pathway, also demonstrate the product was not exclusively marketed in a test market. Products found to be Pre-Existing are not considered a predicate product without this information.

- Dated evidence that shows the product was commercially marketed in the United States as of February 15, 2007.

SUBMISSION CHECKLIST

- ❑ One submission per tobacco product
- ❑ Submission content including evidence in English
- ❑ Submission labeled as a “Pre-Existing Tobacco Product Submission”
- ❑ Applicant name and contact information
- ❑ Name of tobacco product
- ❑ Unique identifying product characteristics
- ❑ Test marketing statement (if applicable)
- ❑ Evidence that product was commercially marketed as of February 15, 2007, in the United States
- ❑ Submit via the CTP Portal (electronic) or CTP Document Control Center (hard copy)

WHERE TO SUBMIT

- If submitting more than one request, each tobacco product should be submitted as a separate Pre-Existing submission.

- Submit electronically via the CTP Portal using FDA's eSubmitter or mail to CTP's Document Control Center (DCC).

- If a submitter does not have a CTP Portal account, one can be created via your organization's Industry Account Manager.

TOBACCO PRODUCT NAME

While a change in a product's name does not create a new product, the name of the tobacco product listed in submission should be the **exact name** of the tobacco product as it was commercially marketed **as of February 15, 2007.** If there is a modification to the product after February 15, 2007, that impacts the characteristics of the product (e.g., changes other than a name change), the product, as modified, can no longer serve as a preexisting tobacco product and premarket authorization is required to market your product in the United States.

NAME AS OF 2/15/2007	**Acme Churchill Robusto 5 Pack**
NAME IN 2019	**Craig's Churchill Robusto 5 Pack**

TOBACCO PRODUCT DESCRIPTION- UNIQUE IDENTIFIERS

UNIQUE PRODUCT IDENTIFIERS

- Identifying characteristics of the product, such as package type, quantity, length, diameter, tobacco cut size, portion mass, and flavor.

- Note that unique product identifiers listed in a Pre-Existing submission will be used as a reference during a substantial equivalence review. A SE tobacco product is one that has been found by FDA to have either the same characteristics as a predicate product or has different characteristics than the predicate tobacco product, but the Substantial Equivalence Report demonstrates that the new product does not raise different questions of public health.

TOBACCO PRODUCT DESCRIPTION CONT'D – PACKAGE TYPE

UNIQUE PRODUCT IDENTIFIERS: PRODUCT PACKAGE TYPE

- Product Package type: As defined in section 900(13) of the FD&C Act, the term “package,” means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers. This is the product’s outer most package type that the product is sold in such as a box, carton, or other container which may not be directly touching the tobacco product.

TOBACCO PRODUCT DESCRIPTION CONT'D

UNIQUE PRODUCT IDENTIFIERS: CONTAINER CLOSURE SYSTEM

- The Container closure system is a subset of the package type defined as any packaging materials that are a component or part of a tobacco product.

- Packaging that constitutes the container closure system is intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the tobacco product (e.g., leaching substances that are then incorporated into a consumable tobacco product).

Example: The carton holding multiple soft packs of cigarettes is considered the package, and each soft pack with surrounding cellophane is considered the container closure system

TOBACCO PRODUCT DESCRIPTION CONT'D

Co-Packaging

- A Co-Package is a tobacco product that is offered for sale containing multiple distinct tobacco products.
- **For Example:** A can of Roll-Your-Own (RYO) tobacco that includes a booklet of rolling paper.

TEST MARKETING INFORMATION - PREDICATE ELIGIBLE

STATEMENT

Not Predicate Eligible:
Affirmative statement that the tobacco product (**including those products in test markets**) under review was commercially marketed, in the United States as of February 15, 2007.

Predicate Eligible:
Affirmative statement that the tobacco product under review was commercially marketed, in the United States as of February 15, 2007, and **was not exclusively in a test market**.

RESPONSIBLE OFFICIAL

Should be from an individual who has knowledge of the test marketing and commercial marketing status of the tobacco product as of February 15, 2007, and has the authority to make such a statement

FULL NAME OF TOBACCO PRODUCT

Product name must match the name identified in the submission and it must be the name of the product as it was commercially marketed in the U.S. as of February 15, 2007

TEST MARKETING STATEMENT EXAMPLES

Not Predicate Eligible:

"I, *(insert name and position title of responsible official)*, confirm that the tobacco product associated with this Pre-Existing Submission, *(insert name of tobacco product as it was on February 15, 2007)*, was commercially marketed in the United States as of February 15, 2007.**"**

Predicate Eligible:

"I, (insert name and position title of responsible official), confirm that the tobacco product associated with this Pre-Existing Submission, (insert name of tobacco product as it was on February 15, 2007), was commercially marketed **other than exclusively for test marketing** in the United States as of February 15, 2007.

John Smith

Vice President

EVIDENCE OF COMMERCIAL MARKETING

EXAMPLES OF DOCUMENTATION OF COMMERCIAL MARKETING

- Dated Copies of Advertisements
- Dated Catalog Pages
- Dated Promotional Material
- Dated Trade Publications
- Dated Bills of Lading
- Dated Freight Bills
- Dated Waybills
- Dated Invoices
- Dated Purchase Orders
- Dated Customer Receipts
- Dated Manufacturing Documents
- Dated Distributor or Retailer Inventory Lists

LINKING INFORMATION

- Each piece of evidence submitted must be dated and have a brief statement or chart that clearly identifies the “link” between any abbreviation, symbol, or reference used in the evidence. This information is referred to as “Linking”.
- Linking information can be provided to explain product name discrepancies.
- Inconsistent naming of the product throughout the submission could possibly result in the FDA sending a Request for Information (RFI).

EVIDENCE OF COMMERCIAL MARKETING

COMMON PUBLIC RESOURCES FOR FINDING COMMERCIAL MARKETING EVIDENCE

Internet Website Archives

Online Libraries

USPTO Trademark Database

United States Copyright Office Copyright Catalog

SEC Edgar Database

Search Engines

REASONS FOR REQUESTS FOR INFORMATION

COMMON REASONS FOR REQUESTS FOR INFORMATION

1	INCONSISTENT NAMING OF THE TOBACCO PRODUCT
2	INADEQUATE EVIDENCE OF COMMERCIAL MARKETING IN THE U.S. **AS OF** FEBRUARY 15, 2007
3	COLLECTIVE EVIDENCE DOES NOT DEMONSTRATE COMMERCIAL MARKETING IN THE U.S. BEFORE **AND/OR** AFTER FEBRUARY 15, 2007

ADDITIONAL RESOURCES

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

SEARCHABLE TOBACCO PRODUCT 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

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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

THANK YOU!

U.S. FOOD & DRUG ADMINISTRATION

Center for Tobacco Products