PRE-EXISTING TOBACCO PRODUCT DETERMINATION PROGRAM WEBINAR SERIES

PART 3 OF 3:

PROCESS FOR AGENCY REVIEW

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

AGENDA

Webinar Overview

1. FDA's Process for Agency Review
2. Requests for Information (RFI)
3. Amending Pre-Existing Submissions
4. Withdrawing Pre-Existing Submissions
5. Types of Agency Determinations
6. Frequently Asked Questions

PROCESS FOR AGENCY REVIEW

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Receipt:

- Once a submission is received, FDA conducts an initial review of the submission to determine whether to accept the submission for review.

Accepted:

- Once a submission is received and accepted, an acknowledgement letter is issued with the official date of receipt and the assigned Submission Tracking Number (STN) beginning with "PX".

Not Accepted:

- If not accepted, an Unable to Accept (UTA) letter is issued.

UNABLE TO ACCEPT LETTER: UTA

- Unable to Accept (UTA) letters are sent when a firm intends to request a Pre-Existing status determination for more than one tobacco product.
- Multiple submissions may be submitted into a single package or envelope, but each Pre-Existing request should be clearly identified in separate documents.
- If issued a UTA letter, the submission may be corrected and re-submitted.

UNABLE TO REVIEW LETTER: UTR

Unable to Review (UTR) letters are issued if the submission fails to include sufficient information for FDA to begin review. UTR Letters may be issued if a submission:

- Is missing commercial marketing evidence
- Is missing unique products identifiers
- Contains information or evidence that needs to be translated into English
- Identifies specific products that are not tobacco products
- Is missing submitter/manufacturer name and contact information

REVIEWING PRE-EXISTING SUBMISSION COMPONENTS

After accepting a Pre-Existing submission, assigning a Pre-Existing Submission Tracking Number (PX STN) and sending an acknowledgement letter, the Pre-Existing submission components are reviewed, including:

- Tobacco product name
- Tobacco product description – Unique Identifiers
- Test marketing statement
- Evidence of commercial marketing as of February 15, 2007
- Linking

TOBACCO PRODUCT NAME

FDA will review the submission for the tobacco product name.

- The name of the tobacco product listed in the submission should be the exact name of the tobacco product as it was commercially marketed as of February 15, 2007.
- The tobacco product name should be consistent throughout the submission.
- If the product name changed after February 15, 2007, the submission should consistently reference the product name as commercially marketed as of February 15, 2007.

TOBACCO PRODUCT DESCRIPTION - UNIQUE IDENTIFIERS

FDA will review the applicant's description of the tobacco product and corresponding unique identifiers.

- Characteristics that uniquely identify a tobacco product include but are not limited to package type, quantity, length, diameter, tobacco cut size, portion mass, and flavor.

- Each tobacco product, such as cigarettes, cigars, smokeless tobacco products, and roll-your-own tobacco products, have their own identifiers.

More information on unique identifiers can be found in the 2021 SE Rule and Table 1 of 21 CFR section 1107.18(c)(7)(iii).

TEST MARKETING STATEMENT

When submitting a standalone Pre-Existing submission, you may submit a test marketing statement.

- A test marketing statement is a statement that the product, including those products in test markets, was commercially marketed in the United States as of February 15, 2007.
- If the pre-existing product is intended to be a predicate product in the Substantial Equivalence (SE) Pathway, the submission must include a statement that the product was commercially marketed (other than for test marketing) in the United States as of February 15, 2007.
- Confirmation should be submitted in the form of a statement from a responsible official who has the proper knowledge of the test marketing status and the authority to make such a statement.

EVIDENCE OF COMMERCIAL MARKETING & LINKING

FDA will review commercial marketing evidence to establish the product was commercially marketed as of February 15, 2007.

- Commercial marketing means 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.
- FDA recommends providing dated evidence showing that the product was commercially marketed in the United States as of February 15, 2007.
- Submission content and evidence should be in English.
- Product name, unique identifiers, abbreviations, symbols or reference used in evidence should be consistent throughout the submission, properly “Linking” the product to the evidence.

REQUESTS FOR INFORMATION (RFI)

REQUESTS FOR INFORMATION (RFI) LETTERS

- The FDA may send a request for information (RFI) letter to the submitter to request additional information to clarify any issues or parts of a submission.

- The submitter will have thirty (30) calendar days from the date the letter was received to respond before FDA continues their review.

COMMON REASONS FOR REQUESTS FOR INFORMATION

- **Name:** The name of the product is inconsistent throughout the submission and remains unclear. The submission should clearly identify the name of the tobacco product as it was commercially marketed in the United State as of February 15, 2007.

- **Unique Identifiers:** The information submitted does not uniquely identify the tobacco product such as package type, quantity, length, diameter, tobacco cut size, portion mass etc.

- **Evidence:** The information submitted does not appear to include adequate evidence demonstrating (individually or collectively) that the tobacco product was commercially marketed in the United States as of February 15, 2007. If you cannot provide documentation specifically dated on February 15, 2007, please provide documentation of commercial marketing for a reasonable period of time before and after February 15, 2007.

COMMON REQUESTS FOR INFORMATION CONTINUED

Test Marketing Statement: If the submission does not include a test marketing statement, an RFI may be issued.

If the submitter intends to demonstrate that the pre-existing product qualifies as a predicate, the Pre-existing submission should include a test marketing statement which states the product was commercially marketed (other than exclusively for test marketing) in the United States as of February 15, 2007.

Example: For a product determined to be pre-existing to also qualify as a predicate, a statement similar to the following should be included in the Pre-existing submission:

> *"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."*

COMMON REQUESTS FOR INFORMATION CONTINUED

Linking: Any evidence provided in a submission should include a brief statement or chart that clearly identifies the "link" between any abbreviation, symbol, or reference used in the evidence that corresponds to the tobacco product under review. Insufficient or inconsistent linking information may result in an RFI.

Example: FDA may issue an RFI if the information submitted does not provide sufficient detail to link a specific line item on a bill of lading, invoice, or other evidence of commercial marketing to the tobacco product under review.

RESPONSES TO RFI LETTERS

- You should provide all requested information.
- FDA will request the information be provided by a due date specified in the letter, generally within thirty (30) calendar days of receipt of the RFI letter.
- For questions regarding RFI Letters you may email CTP-Preexisting@fda.hhs.gov or schedule a teleconference to discuss the requested information prior to the due date.
- After the due date has passed, the FDA will continue its review based on the information received.

AMENDMENTS

AMENDMENTS

- Amendments should clearly identify the information in the original submission that is being amended. Other information, such as test marketing statements and linking information, should be updated as needed to align with the amended information for consistency throughout the submission.

- Firms may amend their submissions prior to receiving a Request for Information.

- Amendments should be submitted either electronically via CTP Portal using FDA's eSubmitter or by mail to CTP's Document Control Center (DCC).

- Amendments should include the assigned STN and "Amendment" in the subject line.

- FDA does not issue acknowledgement letters for amendment submissions.

REQUESTS FOR WITHDRAWAL

WITHDRAWALS

- A submitter can withdraw a pre-existing status determination submission at any time during the review process.

- Withdrawals should be submitted either electronically via CTP Portal using FDA's eSubmitter or by mail to CTP's Document Control Center(DCC). A withdrawal should include the assigned STN and "Withdrawal" in the subject line.

- If a submission is withdrawn, and later resubmitted, a new PX STN will be issued.

PRE-EXISTING DETERMINATIONS

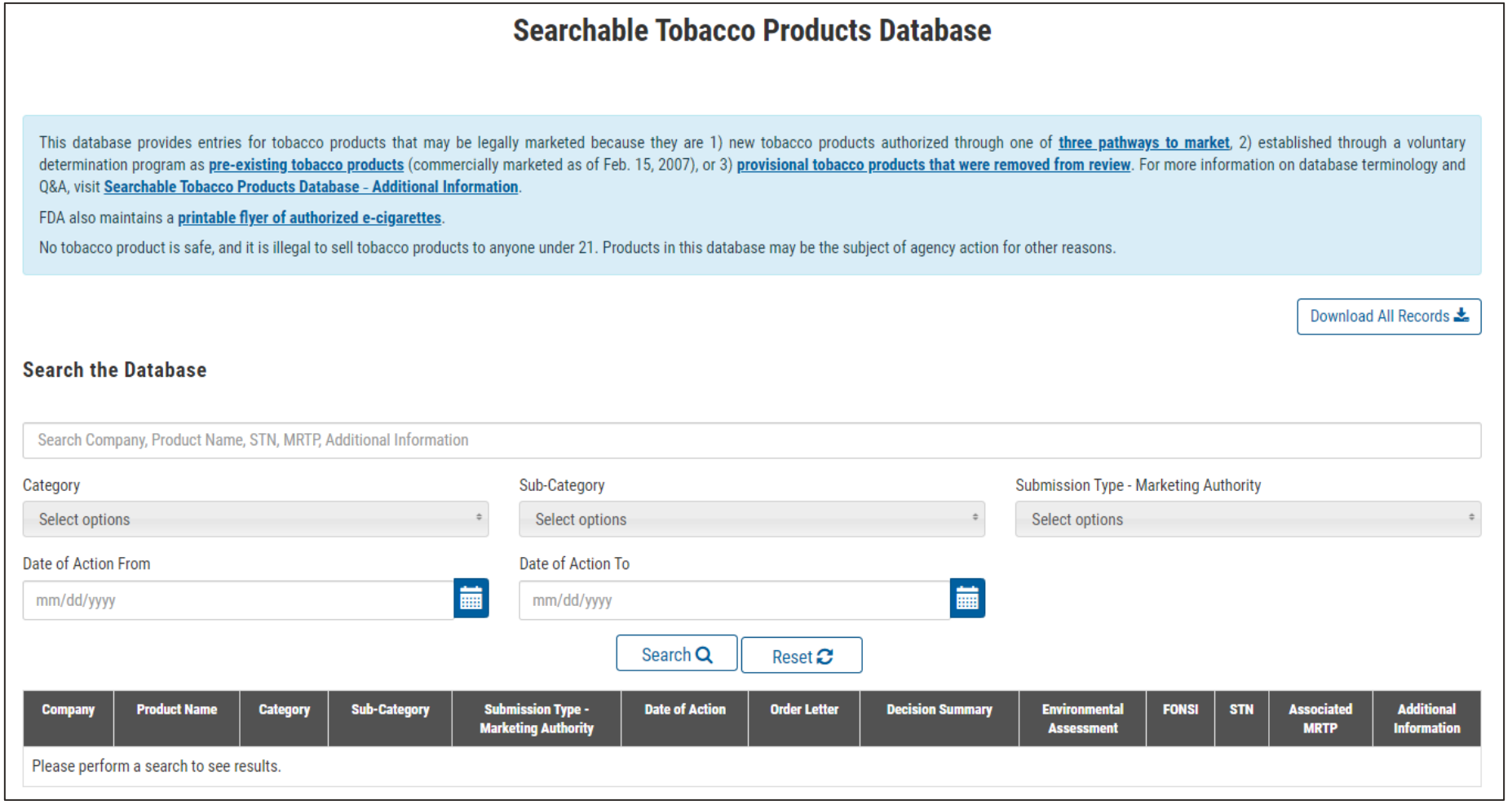
PRE-EXISTING DETERMINATIONS

There are three possible determinations for pre-existing tobacco products:

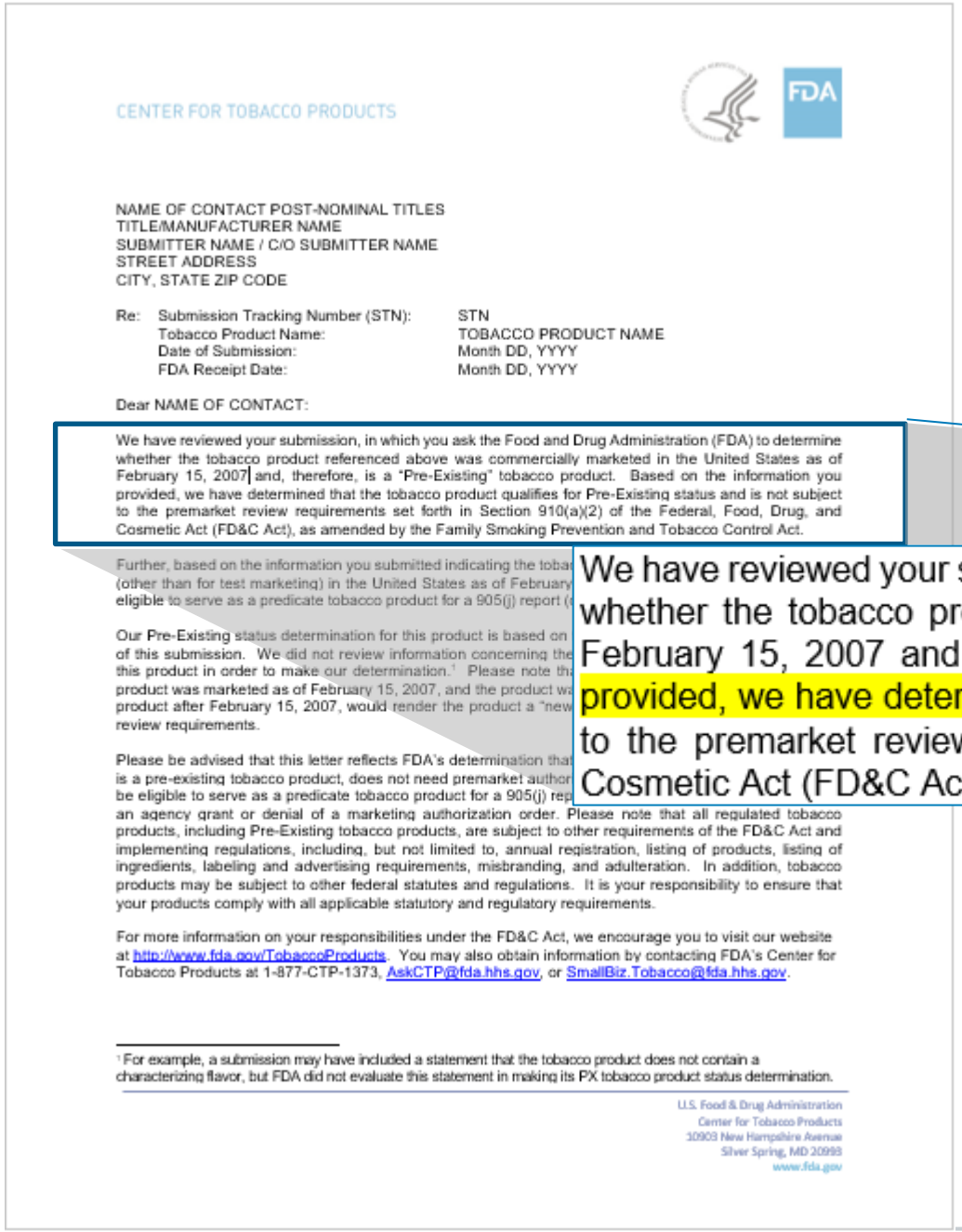
1. The product is determined to be pre-existing but is not predicate eligible
2. The product is determined to be both pre-existing and eligible to serve as a predicate
3. Unable to determine pre-existing status

SEARCHABLE TOBACCO PRODUCTS DATABASE

Located at: www.fda.gov/searchtobacco



Pre-Existing Tobacco Product Status Determination Letter (EXAMPLE)



CENTER FOR TOBACCO PRODUCTS

NAME OF CONTACT POST-NOMINAL TITLES
TITLE/MANUFACTURER NAME
SUBMITTER NAME / C/O SUBMITTER NAME
STREET ADDRESS
CITY, STATE ZIP CODE

Re: Submission Tracking Number (STN): STN
Tobacco Product Name: TOBACCO PRODUCT NAME
Date of Submission: Month DD, YYYY
FDA Receipt Date: Month DD, YYYY

Dear NAME OF CONTACT:

We have reviewed your submission, in which you ask the Food and Drug Administration (FDA) to determine whether the tobacco product referenced above was commercially marketed in the United States as of February 15, 2007 and, therefore, is a "Pre-Existing" tobacco product. Based on the information you provided, we have determined that the tobacco product qualifies for Pre-Existing status and is not subject to the premarket review requirements set forth in Section 910(a)(2) of the Federal, Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act.

Further, based on the information you submitted indicating the toba
(other than for test marketing) in the United States as of February
eligible to serve as a predicate tobacco product for a 905(j) report (

Our Pre-Existing status determination for this product is based on
of this submission. We did not review information concerning the
this product in order to make our determination.[1] Please note tha
product was marketed as of February 15, 2007, and the product wa
product after February 15, 2007, would render the product a "new
review requirements.

Please be advised that this letter reflects FDA's determination that
is a pre-existing tobacco product, does not need premarket author
be eligible to serve as a predicate tobacco product for a 905(j) rep
an agency grant or denial of a marketing authorization order. Please note that all regulated tobacco products, including Pre-Existing tobacco products, are subject to other requirements of the FD&C Act and implementing regulations, including, but not limited to, annual registration, listing of products, listing of ingredients, labeling and advertising requirements, misbranding, and adulteration. In addition, tobacco products may be subject to other federal statutes and regulations. It is your responsibility to ensure that your products comply with all applicable statutory and regulatory requirements.

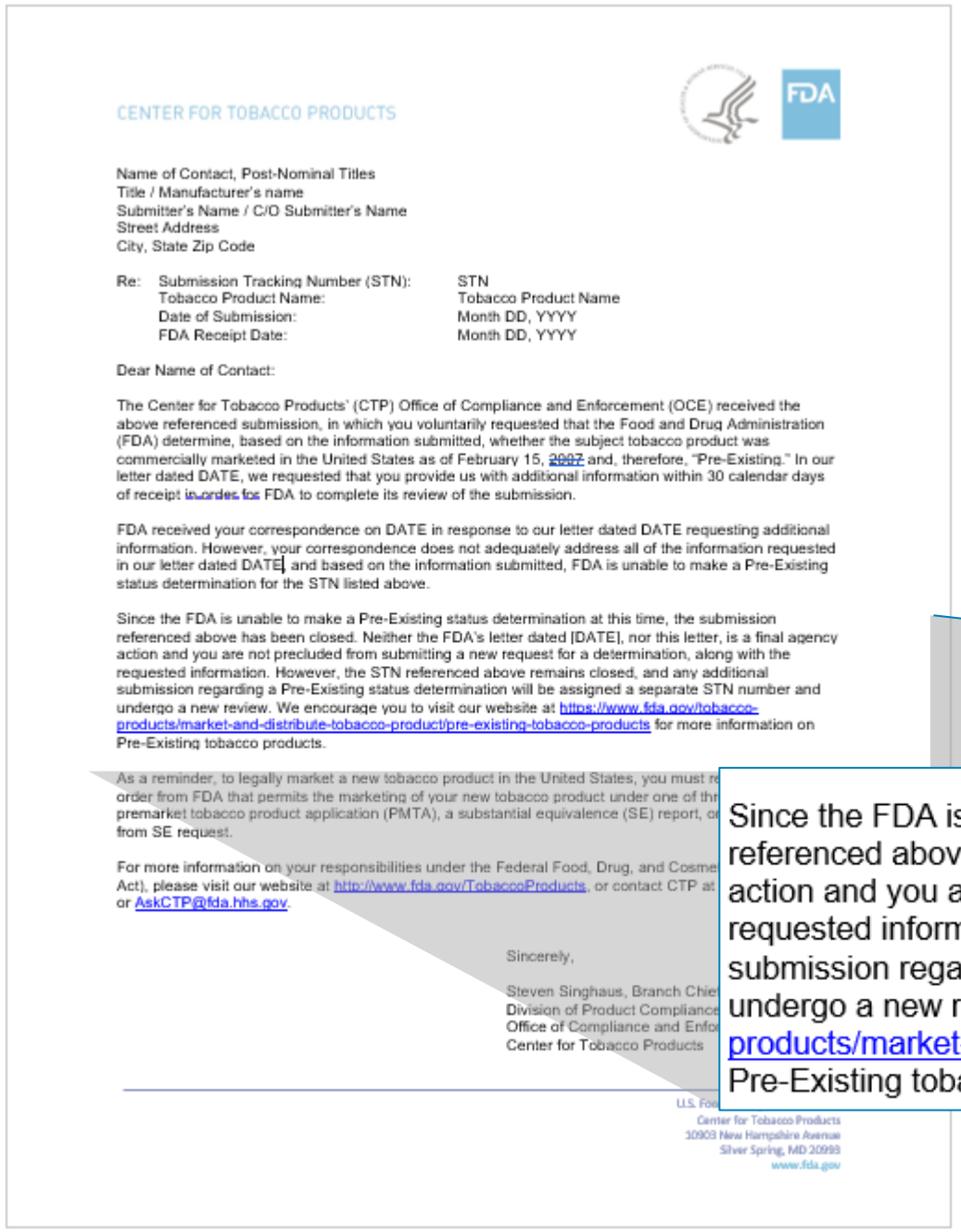
For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

[1] For example, a submission may have included a statement that the tobacco product does not contain a characterizing flavor, but FDA did not evaluate this statement in making its PX tobacco product status determination.

U.S. Food & Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

We have reviewed your submission, in which you ask the Food and Drug Administration (FDA) to determine whether the tobacco product referenced above was commercially marketed in the United States as of February 15, 2007 and, therefore, is a "Pre-Existing" tobacco product. Based on the information you provided, we have determined that the tobacco product qualifies for Pre-Existing status and is not subject to the premarket review requirements set forth in Section 910(a)(2) of the Federal, Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act.

Unable to Determine Pre-Existing Tobacco Product Status Letter (EXAMPLE)



CENTER FOR TOBACCO PRODUCTS

Name of Contact, Post-Nominal Titles
Title / Manufacturer's name
Submitter's Name / C/O Submitter's Name
Street Address
City, State Zip Code

Re: Submission Tracking Number (STN): STN
Tobacco Product Name: Tobacco Product Name
Date of Submission: Month DD, YYYY
FDA Receipt Date: Month DD, YYYY

Dear Name of Contact:

The Center for Tobacco Products' (CTP) Office of Compliance and Enforcement (OCE) received the above referenced submission, in which you voluntarily requested that the Food and Drug Administration (FDA) determine, based on the information submitted, whether the subject tobacco product was commercially marketed in the United States as of February 15, 2007 and, therefore, "Pre-Existing." In our letter dated DATE, we requested that you provide us with additional information within 30 calendar days of receipt in order for FDA to complete its review of the submission.

FDA received your correspondence on DATE in response to our letter dated DATE requesting additional information. However, your correspondence does not adequately address all of the information requested in our letter dated DATE, and based on the information submitted, FDA is unable to make a Pre-Existing status determination for the STN listed above.

Since the FDA is unable to make a Pre-Existing status determination at this time, the submission referenced above has been closed. Neither the FDA's letter dated [DATE], nor this letter, is a final agency action and you are not precluded from submitting a new request for a determination, along with the requested information. However, the STN referenced above remains closed, and any additional submission regarding a Pre-Existing status determination will be assigned a separate STN number and undergo a new review. We encourage you to visit our website at https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/pre-existing-tobacco-products for more information on Pre-Existing tobacco products.

As a reminder, to legally market a new tobacco product in the United States, you must re
order from FDA that permits the marketing of your new tobacco product under one of thr
premarket tobacco product application (PMTA), a substantial equivalence (SE) report, o
from SE request.

For more information on your responsibilities under the Federal Food, Drug, and Cosme
Act), please visit our website at http://www.fda.gov/TobaccoProducts, or contact CTP at
or AskCTP@fda.hhs.gov.

Sincerely,

Steven Singhaus, Branch Chie
Division of Product Compliance
Office of Compliance and Enfo
Center for Tobacco Products

U.S. Foo
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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PROCESS FOR AGENCY REVIEW: FREQUENTLY ASKED QUESTIONS

Who can I contact for a status of my submission?

- FDA generally does not give updates or timelines regarding the review status of a pre-existing tobacco product submission.

Where can I send questions regarding the standalone pre-existing tobacco product review program?

- Email CTP-Preexisting@fda.hhs.gov with your questions, and please include a submission tracking number if you have one.

RESOURCES

Pre-Existing TOBACCO PRODUCT QUESTIONS
Email: CTP-Preexisting@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

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

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

Pre-Existing TOBACCO PRODUCT PROGRAM WEBINAR SERIES
https://www.fda.gov/tobacco-products/compliance-enforcement-training/fda-tobacco-compliance-webinars

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https://www.facebook.com/FDA

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

THANK YOU!

U.S. FOOD & DRUG ADMINISTRATION

Center For Tobacco Products