

THE FOOD AND DRUG ADMINISTRATION (FDA) PART THREE: SUBSTANTIAL EQUIVALENCE (SE): THE PREDICATE REVIEW PROCESS, AMENDMENTS, AND OUTCOMES

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AGENDA:

Presentation Overview

1. **Communications During the Review of a Proposed Predicate**
2. **Common Reasons for an RFI Letter**
3. **Request for Extension of Time to Respond to an RFI**
4. **Changes and Amendments to Predicate Tobacco Product Information**
5. **Outcomes of OCE's Predicate Review**



COMMUNICATIONS DURING THE REVIEW OF A PROPOSED PREDICATE

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Two types of OCE communication may be sent to obtain clarification or additional information during review regarding the tobacco product identified as the predicate:

- Email Correspondence: Email Communications may be sent to the applicant from CTP-Preexisting@fda.hhs.gov regarding issues that are generally limited in scope and requested response time is typically within 7 – 10 business days.
- Requests for Information (RFI): RFI Letters are sent to the applicant to request information to complete the review. The information requests may relate to unique product characteristics, for example. Response time requested is generally within 30 days from receipt.
- Responses should be on Form FDA 3965a and either sent electronically via the CTP Portal or mailed to the address below at the CTP Document Control Center.

Food and Drug Administration Center for Tobacco
Products Document Control Center 10903 New
Hampshire Avenue Building 71, Room G335
Silver Spring, MD 20993-0002

COMMON REASONS FOR A REQUEST FOR INFORMATION (RFI) LETTER

COMMON REASONS FOR AN RFI: UNIQUE CHARACTERISTICS OF THE PREDICATE TOBACCO PRODUCT



- Failure to accurately identify the unique characteristics of the predicate tobacco product, such as package type, quantity, length, diameter, category, sub-category and flavor. The information must be consistent and clear throughout the SE Report submission.
 - *For example, if the information submitted does not clearly identify the predicate's package type or packaging, the applicant will be asked to identify the packaging type.*
- Name of predicate tobacco product is inconsistent or does not match a cross-referenced PX or GF tobacco product.
 - *For Example, XYZ light box vs. XYZ menthol light box.*

COMMON REASONS FOR AN RFI: MISSING OR UNSIGNED CERTIFICATION STATEMENT OF AFFIRMATION



- **Missing Certification Statement of Affirmation:** A missing or incomplete Certification Statement of Affirmation is a common deficiency. This statement certifies that the predicate tobacco product was commercially marketed in the U.S. (other than in test markets) as of February 15, 2007. FDA will confirm a test marketing statement was provided with the submission and signed by a person with knowledge and the authority to make the statement.
- **Missing Signature:** No signature on the test marketing statement will require an RFI.

CERTIFICATION STATEMENT OF AFFIRMATION



- Applicants must provide evidence that demonstrates the tobacco product was commercially marketed in the United States as of February 15, 2007.
- Linking Evidence:
Evidence of commercial marketing must be dated and have a brief statement or chart that clearly identifies the “link” between any abbreviations, symbols, or references used in the evidence of commercial marketing such as an item number and/or product description to the product identified as the predicate in the SE Report.

In addition, the following information should be included in the evidence:

- Ship from and ship to addresses.
- Must be in English or provide translation.
- Must be dated.

REQUEST FOR AN EXTENSION OF TIME TO RESPOND TO AN RFI

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- Rarely, OCE may grant extension requests to respond to email correspondence or RFI Letter:
- Determination on a case-by-case basis.
generally reserved for extenuating circumstances outside the applicant's control such as natural disasters, or other emergencies.
- Requests for extensions will not extend the time for response while the request is being reviewed.
- The applicant will be notified of the decision by mail and, if granted, provided a new due date for response.
- If an applicant fails to respond to the RFI, CTP will review the SE Report based on the information submitted at that time.

CHANGES AND AMENDMENTS TO PREDICATE TOBACCO PRODUCT INFORMATION

21 CFR 1107.20(b)



- As part of the initial Acceptance Review, OS determines if the SE Report is complete. Under 21 CFR 1107.20(b), an applicant may not amend an SE Report to change the predicate tobacco product after OS has accepted the SE Report for review.
- Amending an SE Report to change the predicate may result in NSE or the Applicant may voluntarily withdraw and resubmit the SE Report with updated information.
- Whether an amendment constitutes a change to a predicate is determined on a case-by-case basis. Generally:
 - Examples of amendments that are likely not considered changes to an identified predicate include: correcting typos, minor errors in the predicate tobacco product name, providing supportive evidence of commercial marketing, and Certification Statement of Affirmation (Test Marketing Statement).
 - Examples of amendments that would likely be considered changes to the identified predicate tobacco product include: identifying a different tobacco product to serve as a new predicate product.

OUTCOMES OF OCE'S PREDICATE REVIEW

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- **Predicate eligible** – OCE determines that the product identified in the SE Report can serve as a predicate tobacco product. Review then proceeds to OS to conduct the scientific review. This determination is not considered an SE order at this stage in the review process. There is no marketing authority for the new tobacco product at this stage.
- **Unable to Determine Predicate Eligibility (UAD)** – OCE is unable to determine that the product identified in the SE Report can serve as the predicate tobacco product. OS does not conduct a scientific review, and a Not Substantially Equivalent (NSE) order can be expected. Possible reasons for an UAD determination include (not exhaustive):
 - Failure to respond within due date provided in a RFI letter
 - Failure to correct deficiencies identified in an RFI
 - Change of predicate product after acceptance

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>

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



U.S. FOOD & DRUG
ADMINISTRATION

Center For Tobacco Products