

THE FOOD AND DRUG ADMINISTRATION (FDA) PART ONE: SUBSTANTIAL EQUIVALENCE (SE): KEY CONCEPTS AND OVERVIEW OF THE SE REVIEW PROCESS

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AGENDA:

Presentation Overview

1. Key Concepts and Definitions
2. What is a Predicate Tobacco Product
3. Overview of Changes to the Center for Tobacco Product's (CTP) SE Report Review Process



KEY CONCEPTS AND DEFINITIONS

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- **Predicate Tobacco Product**: A tobacco product identified in an SE Report against which a new tobacco product is compared for purposes of determining substantial equivalence under section 910(a)(3)(A) of the Federal Food, Drug, and Cosmetic Act. 21 CFR § 1107.12.
- **Pre-Existing Tobacco Product**: A common term for a tobacco product that was commercially marketed in the United States as of February 15, 2007. (See 21 CFR § 1107.12 and § 1100.202)
- **Commercially Marketed**: 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 (21 CFR § 1100.202)
 - FDA interprets “as of” February 15, 2007, to mean the product was commercially marketed on that specific date.
 - A product exclusively in test markets as of that date cannot serve as a predicate tobacco product.

WHAT IS A PREDICATE TOBACCO PRODUCT

REQUIREMENTS TO BE A PREDICATE TOBACCO PRODUCT



A Predicate Tobacco Product is a tobacco product that was either 1) commercially marketed (other than exclusively for test marketing) in the United States as of February 15, 2007, (i.e., a “pre-existing tobacco product”) or 2) a tobacco product that FDA has previously found substantially equivalent under section 910(a)(2)(A)(i) of the Federal Food Drug and Cosmetic Act. 21 CFR § 1107.12.

In addition to being either pre-existing or previously found to be substantially equivalent, a predicate tobacco product must be:

- An individual product and not composite of multiple products
- Not subject of a recission action by FDA
- Not removed from the market at the initiative of FDA; and
- Not misbranded or adulterated as determined by judicial order.

(21 CFR §1107.18(f))

OVERVIEW OF CHANGES TO CTP'S SE REPORT REVIEW PROCESS AND COMMUNICATIONS BETWEEN FDA AND APPLICANTS

SE REVIEW PROCESS OVERVIEW



- SE Reports are subject to multiple types of review, each conducted by a different Office within the Center for Tobacco Products (CTP), including the Office of Science (OS) and the Office of Compliance and Enforcement (OCE).
- OS evaluates the scientific information and data in the SE Report (“Scientific Review”) to determine whether the new tobacco product is substantially equivalent to the predicate tobacco product.
- OCE evaluates the eligibility of the predicate tobacco product identified in the SE Report only if it is claimed that the predicate tobacco product was commercially marketed as of February 15, 2007.

SE REVIEW PROCESS OVERVIEW CONTINUED



- Under the SE Rule, acceptance review is conducted first. If the SE Report relies on a preexisting tobacco product as its predicate, and the Report is accepted for review, the proposed predicate is reviewed first, followed by scientific review.
- Before the SE Rule, review of the proposed predicate and scientific reviews were conducted by OCE and OS concurrently.
- After the SE Rule, OCE and OS review sequentially, starting with OCE's review of the identified pre-existing tobacco product's eligibility to serve as the predicate. A scientific review by OS is conducted only after the pre-existing tobacco product has been found eligible to serve as the predicate tobacco product for the SE Report.

COMMUNICATION REGARDING PREDICATE REVIEWS



- Prior to the SE Rule, the predicate and scientific reviews were conducted concurrently, and applicants could expect a single letter from OS containing deficiencies resulting from both reviews.
- Since the SE Rule was implemented, predicate and scientific reviews are conducted sequentially. Because the predicate tobacco product review is conducted before the scientific review, the applicant will receive communication directly from OCE relating to the proposed predicate's eligibility and should respond directly to OCE.

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!

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