Updates on Substantial Equivalence (SE) Reports and the SE Review Process

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Outline

- SE Update
  - Overview & review process
  - Review queue status
  - Performance standards
- Helpful Items for a Successful Application
  - Unique Product Identification
  - Predicate Product Identification
- Grandfathered Determinations

SE UPDATE

SE Overview

- For a determination of substantial equivalence, the manufacturer must demonstrate that the new product has the same characteristics as the predicate tobacco product; or has different characteristics than the predicate tobacco product but the information submitted demonstrates that the new product does not raise different questions of public health

- This means that products brought to market through this pathway will not present more harm to public health than an eligible predicate tobacco product

SE Review Process

- Phase 1: Administrative
  - Step 1: **Application Received** -- FDA receives and processes the application.
  - Step 2: **Acceptance Review** -- FDA reviews the tobacco SE Report to determine if it is under jurisdiction and contains statutorily mandated items.
  - Step 3: **Acknowledgement Letter** -- issues when SE Report meets acceptance criteria
  - Other: **Public Health Impact Review** -- All acknowledged provisional SE Reports have received a public health impact (PHI) review to determine their order in the review queue.

SE Review Process

- Phase 2: Notification
  - Step 4: **Predicate Determination** -- FDA reviews the predicate tobacco product to validate that it is a *bona fide* predicate.
    - A tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007

      OR

    - A product previously found to be substantially equivalent by the FDA
  - Step 5: **Assignment of Scientific Reviewers** -- reviewers assigned based on contents of the SE Report

(Steps 4 and 5 are concurrent)

SE Review Process

- Phase 3: Scientific Review and Issuance of Decision
  - Step 6: **Scientific Review Resulting in Scientific Advice/Information Request Letter or Preliminary Finding Letter** -- FDA performs a scientific review of the tobacco SE report assessing the chemistry, toxicology, and engineering of the tobacco product. Additional scientific evaluation can include social science, addiction, and clinical impact. If necessary, scientific advice/information request and/or preliminary finding letters are issued.
    - If no additional information is needed from the applicant, FDA moves to the next step
  - Step 7: **Scientific Review Resulting in an Order Letter** -- FDA determines whether the new tobacco product is substantially equivalent (SE) or not-substantially equivalent (NSE) to a predicate product.

SE Update

- As of March 24, 2014 CTP no longer has a backlog of regular SE Reports awaiting substantive review
- With the elimination of the regular SE queue to start review…
  - it remains the applicant's responsibility to ensure that each SE report contains all of the information necessary to support a thorough evaluation of an SE submission. If an SE report lacks statutorily required information, CTP can refuse to accept it
  - FDA no longer issues notification letters for regular SE Reports
- An applicant can always withdraw an incomplete application and submit a new application and CTP intends to initiate review of that application upon receipt

SE Update – Online Resources

- CTP has posted resources and information online, such as:
  - Tobacco Product Marketing Orders Webpage
    - Copies of SE order letters
    - Summary of Not Substantially Equivalent (NSE) Determinations
    - Numbers of Final Actions
  - SE Process Review Tool
  - Pathways Website
  - SE Related Guidances

SE Update – Performance Measures

- In April 2014, CTP released performance measures to improve the timeliness and predictability of the review of certain types of tobacco product applications
- Between April 2014 and October 1, 2014, CTP refined tracking systems to improve monitoring progress in meeting the performance goals
- Beginning on October 1, 2014, all the performance goals were implemented

SE Update – Performance Measures

- CTP has identified the following set of measures and timeframes for regular SE Reports for Fiscal Years 2015-2018:

Category	Performance Goal	Submission Cohort
Regular SE Reports	Finalize jurisdiction and completeness review (and issue letter as appropriate) within 21 calendar days of FDA receipt of SE Report	FY15: 50% FY16: 60% FY17: 70% FY18: 80%
	Complete scientific review and issue action letter within 90 days of FDA receipt of original SE Report.	FY15: 50% FY16: 60% FY17: 70% FY18: 80%
Regular SE Report Resubmissions	Complete scientific review and issue action letter within 90 days of FDA receipt of a complete SE Report.	FY15: 50% FY16: 60% FY17: 70% FY18: 80%

Helpful Items for a Successful Application

Unique Product Identification

- FDA needs unique identification of the new and predicate product to understand what is being reviewed
- Unique identification may include, but is not limited to:
  - Brand/Sub-brand
  - Descriptors
  - Product Category (e.g., cigarette)
  - Size (e.g., 100 mm)
  - Weight (e.g., 6 oz)
  - Count (e.g., 100 tubes)
  - Packaging/Container Closure (e.g., plastic can with metal lid)

Predicate Product Identification

- Predicate Tobacco Product
  - A tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007

OR

  - A product previously found to be substantially equivalent by the FDA

- Do you have a stand-alone grandfathered (GF) submission?
- Has the predicate previously been found SE?

Predicate that is Claiming Grandfathered Status

- In Step 4 of the SE review process (Predicate Determination), FDA determines if the predicate is eligible
- The Office of Science requests the Office of Compliance and Enforcement to provide determination if the proposed predicate is claimed as grandfathered
- Upon finding from OCE, the next step in the process occurs:
  - If grandfathered status is established, moves to Step 6, Scientific review
  - If grandfathered status is not established, an appropriate letter issues

(As noted earlier, Steps 4 and 5 are concurrent)