# Reports on Substantial Equivalence (905(j)(1)(A)(i) Reports): An Update

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# Presentation Outline

- Update on Substantial Equivalence Report Review
- Pathways Website
- Common Deficiencies Found in Reports Reviewed to Date

# Options for Marketing New Tobacco Products:

- In general, three pathways to enter commercial distribution as a new tobacco product:
  - (1) new product application (910(b));
  - (2) a report of substantial equivalence and compliance with the Act (905(j)(1)(A)(i)); or
  - (3) exemption from substantial equivalence (905(j)(3), must also report under 905(j)(1)(A)(ii)).
- This presentation focuses on the 905(j) report reviews

# Provisional Reports

Substantial equivalence (SE) reports received before March 23, 2011, for products introduced to market or changed between February 15, 2007, and March 22, 2011, are considered "provisional" and the products covered by those reports can remain on the market unless FDA finds that they are "*not* substantially equivalent." FDA received 3,126 provisional SE reports before March 23, 2011.

# Regular Reports

SE reports that do not meet the statutory definition of provisional are “regular” reports and products covered by those reports cannot be marketed unless FDA first issues a finding of substantial equivalence. Between March 23, 2011, and July 1, 2012, FDA received 390 regular SE reports.

We are currently prioritizing the review of regular reports over provisional reports.

As of July 1, 2012, FDA has :

- Carried out jurisdictional reviews for 3,464 substantial equivalence reports (including 338 of the 390 regular SE reports) with notifications made to the submitters about whether or not their product is currently being regulated by FDA;
- Issued an initial “Completeness Review” on 133 of the regular SE reports;

As of July 1, 2012, FDA:

- Drafted and sent 133 “Administrative Advice and Information Request” letters to submitters who were missing information, requesting clarification or the submission of the missing information;
- Received and processed 130 responses to the “Advice and Information Request” letters; and
- Is proceeding with the scientific evaluation of the amended SE reports.

FDA has:

- Completed the scientific review and mailed "Scientific Advice and Information" letters to submitters for the first batch of reports.

FDA is:

- Continuing to review regular reports and will continue to send out scientific A/I letters where appropriate.

# Feedback to Industry

- As of July 1, 2012, FDA has received 78 requests for meetings from tobacco manufacturers or related trade associations and CTP has granted 59 of the requests.
- Additionally, FDA has developed public webinars to explain our processes and describe the kind of information the Agency needs tobacco manufacturers to submit.

# Feedback to Industry

- FDA is encouraging teleconferences between the assigned regulatory project manager and the applicant.
- FDA has streamlined the SE report review process by modifying the preliminary review so that it focuses only on administrative issues (allowing submission deficiencies to get back to the applicant more quickly).

# Feedback to Industry

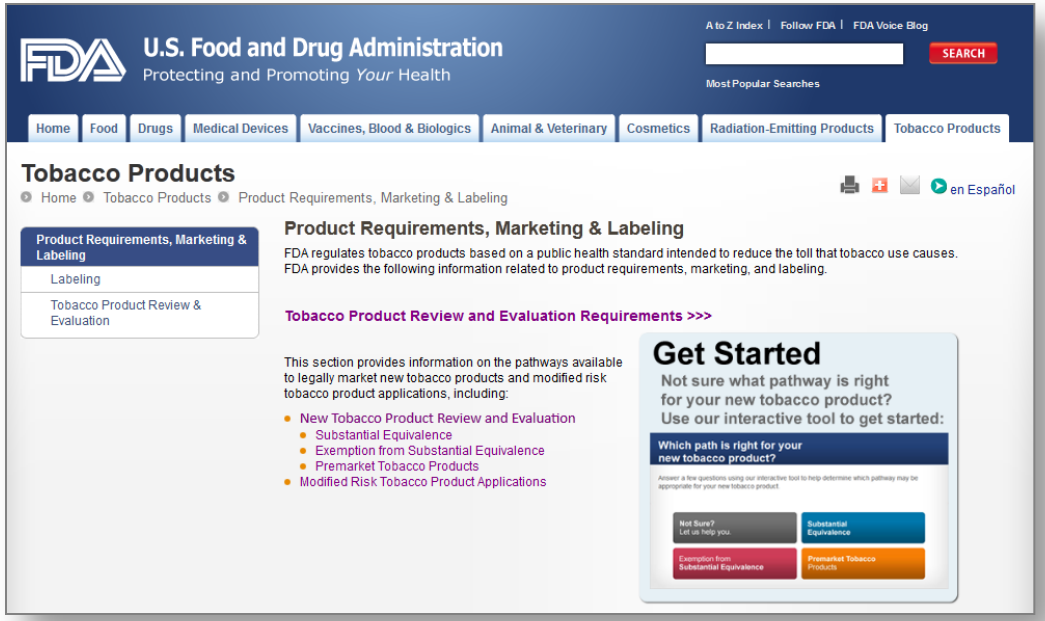
FDA has taken other actions based on industry feedback and questions including:

- Adding information regarding potential contact by Office of Compliance and Enforcement in our acknowledgement letters, and
- Clarifying the wording in our Advice and Information Request letters.

# Pathways to Market

**Tobacco Product Review & Evaluation**

- Launched – August 7
- Explains the three pathways to legally market new tobacco products in the U.S.
- Centralizes key information
- Interactive tool helps users understand their options



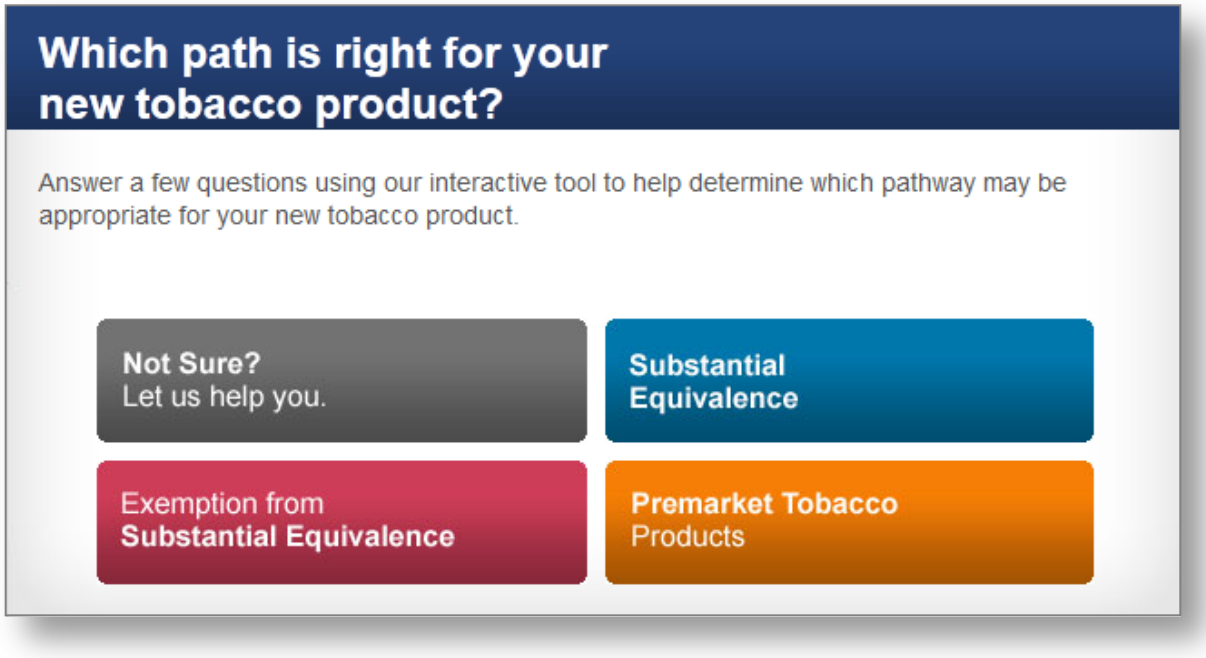

**www.fda.gov/tobacco**

**Click on Product Requirements, Marketing and Labeling**

# Pathways – Interactive Tool

**Tool Benefits**

- Simple yes/no questions
- Easy to navigate
- Directs user to the appropriate pathway
- User can use Back or Start Over buttons to try different scenarios



# Pathways – Key Features


**Links on each page provide easy navigation**

**Callout boxes highlight definitions and important information**

**Links to the exact section of the Act being referenced**

# Common Deficiencies Found in Reports Reviewed to Date

# Scope

- Deficiencies observed in multiple SE reports from different tobacco product manufacturers
  - Based on completed scientific reviews by FDA
  - Have been communicated to manufacturers
  - Significant deficiencies in nearly all SE reports reviewed to date

# Scope

- Deficiencies presented in webinar may not be applicable to all SE reports reviewed by FDA

- Will not discuss deficiencies unique to individual manufacturers or specific product types

# Deficiencies to be Discussed

- Category of SE reports
- Predicate Product
- Identification of Products
- Tobacco Blend

# Deficiencies to be Discussed

- Ingredients and Additives
- HPHCs
- Product Design
- Packaging and Product Stability
- Basis for SE Determination

# Category of SE report

- Two categories:
  - Same characteristics
  - Different characteristics but does not raise public health questions

- Category was not clearly stated in some SE reports

# Category of SE report

- Contradictory statements within SE reports
- Information in some SE reports did not support stated category

# Predicate Product

- Some SE reports identified unacceptable predicate products
  - Predicate has to be a grandfathered product (on the U.S. market on February 15, 2007) or
  - The predicate must have been found to be SE by FDA

# Predicate Product

- Numerous predicate products
  - Multiple predicates allowed
  - January 2011 SE guidance recommends one predicate
    - SE determination difficult if numerous predicate products

# Predicate Product

- Rationale for selection of predicate product unclear
  - Some predicate products did not seem appropriate
    - e.g., Filtered cigarette as predicate for unfiltered cigarette

# Identification of Products

- This deficiency applied to both predicate and new products

- Unique identifiers not always submitted
  - Some new and predicate products had same identifier

# Tobacco Blend

- Tobacco type, quantity, curing method provided but other information about tobacco not provided
  - e.g., Additives applied directly to tobacco blend prior to addition to tobacco product
  - e.g., Details about different reconstituted tobaccos

# Tobacco Blend

- Not enough information to understand how tobacco differences affect product characteristics
  - e.g., Tobacco appears identical in new and predicate products but significant differences in HPHCs

# Ingredients and Additives

- Inadequate information to completely understand product composition
- Specifications used by manufacturers were not always provided
  - e.g., tobacco grading system, ingredient grade
- Ingredients not always identified for each product component/material

# Ingredients and Additives

- Ranges in quantity not always provided
  - Appeared that mean or target values presented
  - Explanation of range or acceptance limits for each ingredient and additive not provided
- Multiple sources of ingredients
  - Unclear how different sources used
  - Inadequate information to compare sources

# Ingredients and Additives

- Interchangeable ingredients
  - Unclear why and how ingredients used
  - Inadequate information to compare ingredients

# HPHCs

- Not submitted in some SE reports
  - Not required but recommended in January 2011 guidance
  - Some SE reports cited section 915 of FD&C Act as providing delays in reporting HPHCs
    - However, section 915 of FD&C Act does not impact SE reporting requirements in sections 905 and 910 of FD&C Act
- Explanation for differences in HPHC quantities not provided

# HPHCs

- Number of replicates too small
- Information to evaluate data missing
  - Test method
  - Test date(s)
  - Manufacture date(s)
  - Product storage conditions
- HPHCs in smoke from multiple smoking regimens not provided

# Product Design

- Schematics of product not provided
  - Unclear how materials/ingredients used in product
- Inadequate product attributes to understand product engineering
  - Information was often limited to differences in new & predicate products

# Product Design

- Release specifications not provided
  - Difficult to understand how product quality/consistency maintained
- Testing data not submitted
  - Test method
  - Test date(s)
  - Manufacture date(s)
  - Product storage conditions
  - Pass/fail criteria

# Packaging and Product Stability

- Packaging specification not provided
  - Materials/ingredients
  - Test data
- Submitted stability data was often based on consumer perception
  - Not a measurement of public health impact

# Basis for SE Determination

- Claimed same characteristics in spite of different product composition and design
- SE reports cited historical knowledge of the manufacturer but did not provide data/information to support
  - Manufacturers may understand impact of product characteristic changes
  - FDA does not understand impact without data/information

# How Can Industry Facilitate FDA Review of SE Reports?

- Submission of separate 905(j) reports for each unique product
- Submission of a separate request for grandfather determination to the Office of Compliance and Enforcement at FDA could speed up the review process
- Organize the content of the 905(j) report as described in the January 5, 2011, final guidance

# How Can Industry Facilitate FDA Review of SE Reports?

- Inclusion of all content described in the January 5, 2011, final guidance
  - Include a statement if any item is not applicable (e.g., heat source not applicable for smokeless tobacco product)
  - Include levels of HPHCs
- Increase communication with assigned regulatory health project manager

# How Can Industry Facilitate FDA Review of SE Reports?

- Ensure your report is current regarding your authorized official (to whom we will issue correspondence) and other authorized contacts

# Questions?

If you have a SE report at FDA, please contact your assigned regulatory health project manager.

If you do not have an SE report at FDA, contact:

CTP Call Center: 1-877-287-1373 (9:00am – 4:00pm ET)

AskCTP@fda.hhs.gov

For further information:

http://www.fda.gov/TobaccoProducts/ResourcesforYou/ForIndustry/ucm238891.htm