

# **Reports on Substantial Equivalence (905(j)(1)(A)(i) Reports): One Year Later**

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***Cristi Stark, MS***

***Lead Regulatory Health Project Manager***

***Office of Science***

***Center for Tobacco Products***

# Presentation Outline

- Background on Substantial Equivalence
- What Should be Included in the Report
- Substantial Equivalence Process
- Lessons Learned
- Industry Considerations

# Options for Marketing New Tobacco Products:

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

# What is a New Tobacco Product?

- Section 910(a) of the Tobacco Control Act defines “new tobacco product” as:
  - (A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

# New Tobacco Product (cont'd):

- Section 910(a) defines “new tobacco product” as:
  - (B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

# Substantial Equivalence (SE)

# Substantial Equivalence Overview

- Outlined in the Food Drug and Cosmetic Act (FD&C Act)
  - Section 910
  - Section 905(j)
- Final Guidance for Industry issued on January 5, 2011
  - To clarify what industry should include to demonstrate a scientific finding of substantial equivalence
- Draft Guidance for Industry issued September 2011
  - To clarify frequently asked questions FDA had received around substantial equivalence

# Enforcement Discretion

- Tobacco blending changes required to address the natural variation of tobacco (e.g., blending changes due to variation in growing conditions) in order to maintain a consistent product
- Components of regulated tobacco products that are sold or distributed solely for further manufacturing into finished tobacco products



# Types of SE Reports

- Provisional Reports
  - referred to as interim/new tobacco products in Jan 2011 presentation
    - New tobacco product introduced into commercial distribution 2/16/07-3/21/11; AND
    - SE Report submitted by 3/22/11
- Regular Reports
  - Does not fit criteria for provisional reports

# Composition of an SE Report

# Items to Include in your SE Report

- Cover letter
- Summary Section
- Identification of your new tobacco product
- Identification of your predicate(s) product

# Items to Include in your SE Report (2)

- Applicant basis for determination that product is SE
  - Characteristics compared with predicate:
    - Same characteristics
    - Different characteristics that do not raise different questions of public health
  - Rationale
- Health Information Summary (Section 910(a)(4))
- Action to comply with Section 907
- Environmental Assessment (21 CFR 25.15)

# Items to Include in your SE Report (3)

- Characteristics
  - Ingredients
  - Materials
  - Design Features
  - Heating Source
  - Composition
  - Other Features
    - Harmful and Potentially Harmful Constituents (HPHC)
    - Other
- Additional Data

# SE Review Process

# Regular Reports (current approach)

- Has taken priority over provisional reports
  - Need an order finding new tobacco product SE to legally market product in United States
- Reviewed in first-in-first-reviewed order
- Review order has been based on the date a 905(j) is received by FDA

# SE Review Process

- Submitted by Applicant
- Received by Document Control Center and stamped with date of receipt
- Sent to Office of Science for RHPM Assignment
- RHPM reviews and acknowledges report
- SE report assigned out for technical and scientific review while regulatory review performed



# SE Review Process (2)

- Regulatory Review
  - RHPM reviews completeness according to statutory requirements
  - Where information is missing, an advice/information request letter has been issued requesting missing items or location of items not found (30 day turnaround)

# SE Review Process (3)

- Technical Review:
  - Grandfather determination (if applicable) by Office of Compliance and Enforcement
    - May speed up if receive grandfather determination from OCE separately
  - Compliance with the Act by Office of Compliance and Enforcement

# SE Review Process (4)

- Scientific Review
  - Required reviews assigned:
    - Chemistry
    - Engineering
    - Toxicology
    - Environmental Science
  - Other reviewers assigned as appropriate
    - Depending on contents of report
  - Any deficiencies triggers a scientific advice/information request letter (recent letters have provided for a 30 day turnaround)

# Lessons Learned

# RHPM Assignment

- RHPM's have been reassigned to brands and applicants
  - Allow for direct and consistent contacts for all aspects of the tobacco product

# Modifications to the Most Recent Letters

- Due to questions from industry:
  - Addition of language regarding potential contact by Office of Compliance and Enforcement in acknowledgement letter
  - Modifications to wording in advice/information request letters for clarification
  - Changes to timelines on responses requested

# Increased Communication

- Encourage teleconferences between assigned RHPM and applicant
- Addition of team lead for responses to questions
- Participation with subject matter lead for unanswered questions and meetings

# Streamlined Review Process

- Due to response from industry:
  - Modification to preliminary review
  - Earlier assignment out for technical and scientific reviews
  - Modifications to timelines for response turnaround



# Industry Considerations

# How Can Industry Facilitate FDA Review of SE Reports?

- Submission of separate 905(j) reports for each unique product
- Submission of request for grandfather determination outside of 905(j) report
- 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? (2)

- Inclusion of all content described in the January 5, 2011 final guidance
  - Include a statement if any item is not applicable
  - Include HPHCs
- Increase communication with assigned regulatory health project manager

# 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](mailto:AskCTP@fda.hhs.gov)

[SmallBiz.Tobacco@fda.hhs.gov](mailto:SmallBiz.Tobacco@fda.hhs.gov)

For further information:

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