Tobacco and Nicotine Products Regulation and Policy Conference

Substantial Equivalence – Where Are We?

Barry S. Schaevitz, Esq.
Fox Rothschild, LLP

FDLI

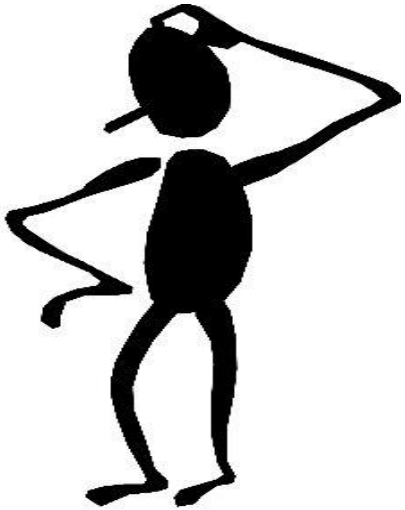
The Tobacco Control Act

- TCA sec. 910(a)(3)
  - Substantially equivalent or substantial equivalence means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product –
    - Has the **same characteristics** as the predicate tobacco product; or
    - Has **different characteristics** and the information submitted contains information, including clinical data if deemed necessary by the Secretary , that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise **different questions of public health**

Important Definitions

- “Same characteristics”
  - ???????
- “Different characteristics”
  - ????????
- “Different questions of public health”
  - ????????

Where does this leave us?



SE Timeline

- *January 2011*- First SE Report Guidance
- *March 2011*- Provisional SE Reports Due
- *April 2018* - ~1500 Provisional Applications "removed from review"
- *October 2018* - Appendix Documents Released
- *April 2019* - Proposed Rule on Format and Content of SE Reports

SE Report Statistics

- Provisional SE Reports
  - ~3600 filed
  - As of April 2018
    - **847 withdrawals**
    - 107 SE orders
    - 84 NSE orders
    - 23 cancellations
    - 14 Refusal-to-Accepts
  - April 2018
    - FDA removed approx. 1500 Provisional SE Reports from review
      - FDA determined were “less likely” to raise different questions of public health

SE Report Statistics

- Reports Filed
  - Over 3,000 SE Reports
    - 96% closed
  - Over 3,600 Provisional SE Reports
    - 83% closed
  - Over 500 EX Requests
    - 85% Closed
- SE Report Withdrawals
  - 2,136
- Decisions
  - 1,120 SE Orders
  - 416 NSE Orders
  - 263 EX Orders
  - 12 NEX Orders

New Information

- Provisional SE Reports Removed from Review
  - "Less likely" to raise different questions of public health
  - Explanation for determination
    - "With the years of experience conducting thousands of SE reviews, and with a greater understanding of tobacco products"

New Information

- October 2018 -- Appendix Documents of “Common Deficiencies”
  - One Appendix for each category of product: All begin with the following phrase “The information included in this appendix reflects deficiencies frequently seen in previous SE Reports for ____that FDA has reviewed.”
  - At the time released to the public, FDA had issued one product quantity change SE for a cigar; no SE Orders for pipe tobacco, and no SE Orders for waterpipe tobacco
  - The Cigar Appendix addressed topics such as:
    - Selection of a predicate product
    - Adequate tobacco and ingredient information
    - Complex ingredients
    - TPMFs
    - Addressing toxicity because of ingredient changes
    - Use of interchangeable materials
    - Nicotine yields
    - HPHC yields
    - Use of Quantitative Risk Assessment or Modeling
    - Product Stability
    - Environmental Assessments

New Information

- Science Memos
  - 22 Memos released in July 2019 detailing criteria used to evaluate SE Reports
    - General (unique characteristics of tobacco products)
    - Chemistry/Toxicology (e.g., equivalency testing, surrogate tobacco products)
    - Engineering
    - Social Science (product quantity, package shape)
    - Behavioral and Clinical Pharmacology
    - Microbiology

New Information

- Science Memos
  - Examples of important policy issues
    - "Characterizing Flavor" --
      - "For each tobacco product, this is indicated by chemical composition, olfactory response, tobacco product labeling, or a combination of any of the three. For an acceptance review it may be noted as described by the submitter/manufacturer. However, any order issued will note the characterizing flavor as determined by FDA."
    - Product Quantity Change –
      - "based upon the currently available science and CTP's experience in reviewing SE Reports, from a Social Science perspective, product quantity changes do not cause new tobacco products to raise different questions of public health."

Proposed SE Rule

- "Same characteristics"
  - "FDA *is considering* whether the 'same characteristics' prong *might be appropriate* for new tobacco products that are so similar to the predicate product that FDA would not need scientific information to determine whether the new product raises different questions of public health."
- "Different characteristics"
- "Different questions of public health"

Proposed SE Rule

- “Same characteristics”
- “Different characteristics”
  - “*Under this approach*, a new product would have ‘different characteristics’ if a product were dissimilar enough from the predicate product that FDA could not determine without scientific information whether the new product raised different questions of public health.”
- “Different questions of public health”

Proposed SE Rule

- "Same characteristics"
- "Different characteristics"
- "Different questions of public health"
  - "In determining if a new product raises different questions of public health, FDA *may consider, among other things*, whether one or more of the following is the case as compared to the predicate product,
    - The new product has the potential to increase HPHC yields, and, if so, the degree of such an increase;
    - The new product has the potential to increase toxicity;
    - The new product has the potential to increase initiation;
    - The new product has the potential to increase abuse liability;
    - The new product has the potential to increase dependence;
    - The new product has the potential to decrease cessation."

Proposed SE Rule

- Main Content
  - New and Predicate Tobacco Product Description
  - Comparison Information
    - Product Design
    - Product Composition
    - Other Features
      - HPHC Testing
      - Stability Testing
  - Comparative Testing Information
  - Environmental Assessment

Proposed SE Rule

- Other thoughts to consider
  - Certification to identical characteristics
    - Will not have to establish that certain characteristics have not changed
  - Review cycles, timeframes and changing review policies
    - New proposed policy of one supplemental submission and no extension of response time
  - Categorical approach to certain modifications
    - Same modification is routinely made to a number of products