Swedish Match®

Meeting with OMB Office of Information and Regulatory Affairs

Nov. 13, 2018

Swedish Match USA, Inc.

FOIA EXEMPT (5 U.S.C. § 552(b)(4))

Background and Information

- Swedish Match is a tobacco product manufacturer and importer which values responsible marketing of tobacco products
  - Portfolio includes smokeless tobacco, non-tobacco nicotine pouch products (ZYN), and cigars
  - Supports and strictly abides by the "non-economic" provisions of the STMSA governing marketing restrictions intended to prevent youth access
  - Supports the goals of the Family Smoking Prevention and Tobacco Control Act (TCA) and the implementation of regulations and policies that sustain competition and legitimate trade while advancing the public health goals of the TCA

Background and Information

- Swedish Match offers a unique voice and perspective for OIRA to consider in reviewing the "Format and Content of Reports Intended to Demonstrate Substantial Equivalence" proposed rule, and has been engaged in such issues since enactment of the TCA
  - Grounded in FDA law and practice
  - Focused on offering FDA means for efficient, effective, and transparent regulations that will stand the test of time
  - Commitment to help FDA understand the nuances and complexities of the tobacco manufacturing industry

Premarket Review Challenges

- FDA's Comprehensive Regulatory Plan
  - "I have asked CTP to consider whether its current plan, which is to review all of the so-called Provisional Substantial Equivalence products, is an effective use of its resources and whether it should continue to pursue the current approach to these reviews. I have asked CTP to consider whether there is an approach that makes more sense, and whether by not reviewing some of those products, those review resources could be free up for other purposes and greater clarity could be provided to the market."
- We are grateful that Commissioner Gottlieb has acknowledged the inefficiencies and unnecessary burdens on both FDA and industry imposed by the current approach to premarket review

Premarket Review Opportunities

- Swedish Match offered a proposed model of premarket regulation in 2011 that we believe will allow FDA to effectively use its resources and provide greater clarity to industry
  - March 2011 Comment Letter (Dockets FDA-2010-D-0635 and FDA-2010-N-0646)
  - December 2017 Comment Letter (Docket FDA-2017-N-5093)
- Summary
  - Draw lessons of the 510(k) premarket review program for medical devices
  - Vest manufacturers with the responsibility to determine whether a particular modification requires a Substantial Equivalence Report
  - Focus premarket review resources on the changes to tobacco products that truly raise different questions of public health

Premarket Review Opportunities

- While FDA may have been unwilling to adopt this framework in 2011 due to a lack of knowledge regarding the industry, the Agency now possesses the experience to adopt this approach, including with respect to deemed tobacco products
  - On April 5, 2018, the Center for Tobacco Products (CTP) removed "about 15,000 SE applications from review because the agency concluded that these products are less likely to raise different questions of public health."
  - The purpose of this action was to "focus resources on provisional product reviews that are likely to raise more significant public health questions – rather than those that don't."

Backlog

- The numbers speak for themselves; in the seven years since provisional SE Reports were due, FDA has completed review of only 47 percent of product applications
  - 7,191 product applications since program inception (premarket applications, regular and provisional SE Reports, SE Exemption Requests, modified risk submissions) and 3,381 Final Actions
- Once refuse-to-accept, refuse-to-file, withdrawals and cancellations are removed from the total number of "Final Actions," FDA's completion rate falls to 7.7 percent

Premarket Review Opportunities

- Certain changes should be categorically exempt
  - Packaging and Quantity changes not impacting the characteristics of the product at issue
  - Changes mandated by law, including tobacco product standards
  - Supplier changes, including changes to or changes implemented by third-party vendors that do not impact the manufacturer's specifications for the product at issue
  - Product specification changes that do not affect TNCO yields or HPHCs or other minor changes that have no public health impact
- Develop product-class specific guidance
- FDA premarket review should not be used as a substitute for current Tobacco Product Manufacturing Practice regulations

Withdrawn SE Proposed Rule

- Issues in the withdrawn SE proposed rule should be addressed in the new SE proposed rule
  - Define key terms and clarify the Agency's approach
    - "Same characteristics"
    - "Different characteristics"
    - "Different question of public health"
      - Questions of public health unlike those currently associated with the class of products
  - Product quantity and packaging changes
    - Clarify that Agency's approach to packaging and container closure system require premarket review only in limited circumstances
- Other tools established in the TCA to address concerns unrelated to marketing of a new tobacco product

Promoting Regulatory Efficiency

- The SE proposed rule should provide opportunities for meaningful engagement during premarket review, which would reduce administrative burdens on industry and Agency review staff, consistent with Executive Orders 13771 and 13777
  - Opportunities to seek clarification and provide requested data
  - Scientific review questions in connection with a change for which scientific evidence support a preliminary determination that a change may raise different questions of public health
  - FDA's current approach is to limit to three review cycles with abbreviated response times

Premarket Review

- In sum, FDA premarket review should be guided by the following principles:
  - Premarket review should be focused on changes that can reasonably be expected to impact the public health
  - Premarket review should not capture ephemeral changes to a product's characteristics; FDA should focus on the permanency of the change at issue
  - FDA has the authority to take a product category-specific approach
  - Premarket review requirements, processes, and acceptance criteria need to be transparent to industry and applied in a consistent, predictable manner

Conclusion

- Swedish Match thanks OMB and Administrator Rao for this opportunity to share views and concerns