



October 30, 2018

Neomi Rao
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget,
NEOB, Room 10202
725 17th Street NW
Washington DC 20503

Re: Request for Meeting to Discuss the “Format and Content of Reports Intended to Demonstrate Substantial Equivalence” Proposed Rule (RIN 0910-AH89)

Dear Administrator Rao:

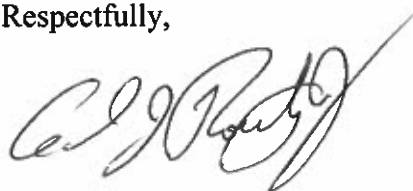
Swedish Match USA Inc. (“Swedish Match”) is a tobacco product manufacturer and importer with concerns regarding the U.S. Food and Drug Administration’s (“FDA’s”) effort to implement the provisions of the Federal Food, Drug, and Cosmetic Act (the “FDCA”), as amended by the Family Smoking Prevention and Tobacco Control Act (the “Tobacco Control Act”). We understand a proposed rule, “Format and Content of Reports Intended to Demonstrate Substantial Equivalence” is currently under review by the Office of Information and Regulatory Affairs (“OIRA”). We write to request an opportunity to meet with OIRA to discuss the proposed rule, as we believe no other stakeholder shares our perspective and experience on these issues.

Swedish Match has been deeply engaged on regulatory and scientific issues before FDA since enactment of the Tobacco Control Act, and believe we can offer unique and practical insights as to how FDA may most effectively utilize its resources in conducting premarket review of new tobacco products. In fact, Swedish Match has long predicted the inefficiencies and strains on review staff that have resulted from FDA’s approach to premarket review, first identifying them in a comment letter submitted on March 3, 2011.¹ We have consistently raised our concerns regarding the premarket review process, particularly FDA’s approach to substantial equivalence and requests for minor modification exemptions, in additional comment letters. In each case, Swedish Match proposed reforms that would allow FDA to establish a premarket review regime that would provide for the more effective and efficient regulation of tobacco products, consistent with the Agency’s public health mission and Executive Orders 13771, “Reducing Regulation and Controlling Regulatory Costs,” and 13777, “Enforcing the Regulatory Reform Agenda.”

¹ Comment of King Maker Marketing, Inc.; Commonwealth Brands, Inc.; JT International U.S.A., Inc.; Sherman’s 1400 Broadway NYC, Ltd., Swedish Match North America, Inc., Substantial Equivalence Guidance Proposed Rule on Substantial Equivalence Exemption – Dockets FDA-2010-D-0635 and FDA-2010-N-0646 (Mar. 3, 2011), available at <http://www.regulations.gov/document?D=FDA-2010-N-0646-0006> (last accessed 10/26/2018).

We appreciate your consideration of our request and look forward to the opportunity to meet with you. We believe that, given our longstanding commitment and attention to these issues, you will find that such a meeting would be productive and informative. Please feel free to contact me directly at (804) 787-5177 or gerry.roerty@swedishmatch.com. Thank you for your assistance.

Respectfully,

A handwritten signature in black ink, appearing to read "Gerard J. Roerty, Jr.", written in a cursive style.

Gerard J. Roerty, Jr., Esq.
Vice President, General Counsel & Secretary
Swedish Match USA Inc.

cc: John R. Manthei
J. Benneville Haas
Latham & Watkins LLP
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