

## Topics for Discussion

1. The proposed scope of the rule covers finished and bulk tobacco product manufacturers, including specification developers. Does the committee have any recommendations on the scope, including expanding the scope?
2. Does the committee have any recommendations or comments on the “umbrella” approach that proposes requirements in flexible terms to enable manufacturers who are subject to the rule to establish procedures that are appropriate for their specific products and operations?
3. Does the committee have any recommendations on the product specifications that FDA proposes to require in the MMR?
4. Does the committee have any recommendations on the proposed design and development activities and risk management process to control risks associated with finished and bulk tobacco product and its production processes, packing, and storage?
5. Does the committee have any additional recommendations on the requirements of the proposed rule?