CONTENT FOCUS: REQUEST FOR EXEMPTION FROM SUBSTANTIAL EQUIVALENCE (EXEMPTION REQUESTS)

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AGENDA

– Key Regulatory Information on the Exemption Request Pathway

– Information to Include in Exemption Request Submissions

– Examples of Possible Exemption Request Modifications

– Examples of Reasons for Refuse to Accept (RTA) Letters
DEFINITION OF A NEW TOBACCO PRODUCT

• A *New Tobacco Product* as defined by Section 910(a)(1) as:
  
  – any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007;

  or

  – 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.
• **Tobacco Products, Exemptions From Substantial Equivalence Requirements**
  – 21 CFR 1107.1(b): Effective August 4, 2011

• An Exemption Request must include, among other information, the following:
  
  (1) a detailed explanation of the purpose of the modification
  
  (2) a detailed description of the modification
     - statement as to whether the modification involves adding or deleting a tobacco additive or
     - statement as to whether modification involves or increasing or decreasing the quantity of an existing tobacco additive
  
  (3) why the modification is a minor modification of a tobacco product
  
  (4) why a report under Section 905(j)(1) of the FD&C Act is not necessary to ensure the protection of public health
  
  (5) an environmental assessment
WHAT IS AN ADDITIVE?

• Additive:
  – The term ‘additive’ means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical – section 900(1) of the FD&C Act
• Applicant contact information

• Table identifying unique identifying properties of the new and original tobacco products (e.g., product name, category, package type, etc.)

• Eligibility of the original tobacco product (e.g., grandfathered, previously found SE)
  – Statement identifying the commercial eligibility of original tobacco product along with intended marketing of both the new and original tobacco products if an Exemption Request order is issued
### EXAMPLE OF UNIQUE IDENTIFICATION INFORMATION

<table>
<thead>
<tr>
<th>Tobacco Product Name</th>
<th>New Product</th>
<th>Original Product</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cigarette A</td>
<td>Cigarette B</td>
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<table>
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<tr>
<th>Tobacco Product Category</th>
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<td></td>
<td>Cigarette</td>
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<table>
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<tr>
<th>Tobacco Product Subcategory</th>
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<tbody>
<tr>
<td></td>
<td>Combusted Filtered</td>
<td>Combusted Filtered</td>
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<table>
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<tr>
<th>Package Type</th>
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<td>Box</td>
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<thead>
<tr>
<th>Package Quantity</th>
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<tbody>
<tr>
<td></td>
<td>20 cigarettes</td>
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<tr>
<th>Length</th>
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<td></td>
<td>84 mm</td>
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<th>Diameter</th>
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<td>7.9 mm</td>
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<th>Ventilation</th>
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<td></td>
<td>10%</td>
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<th>Characterizing Flavor</th>
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<tbody>
<tr>
<td></td>
<td>None</td>
<td>Menthol</td>
</tr>
</tbody>
</table>
USEFUL INFORMATION TO FACILITATE EXEMPTION REQUESTS REVIEW

- Statement of the proposed modification
- Statement of the purpose of proposed modification

- Description of the proposed modification
  - Explain why the modification is a minor modification of a tobacco product and why the modification does not affect other characteristics of the tobacco product
  - A table that compares additives between the new and original tobacco products are helpful to demonstrate this

- Discussion and justification why a SE Report is not necessary
- Inclusion of an environmental assessment
• The proposed minor modification being made is to:
  – Delete additive A
  – Add additive B
  – Increase the quantity of the existing additive C
  – Decrease the quantity of the existing additive D

• The purpose of the proposed modification is to:
  – Delete additive A and add additive B due to a change in supplier
  – Increase additive A and decrease additive B due to state compliance mandates
  – Delete additive D due to additive D no longer being commercially available
• Modifications that *may be* appropriate for Exemption Requests:
  – Change in additive quantity of the same additives from different sources if grade/purity are identical
  – Change in additive quantity of different additives with same function if grade/purity are identical (i.e., interchangeable additives)
  – Change to additives in packaging that are not expected to impact the properties of the tobacco product
  – Replacement of non-FSC cigarette paper with FSC cigarette paper
  – Removal of complex additives or flavors (e.g., menthol)
  – Addition or deletion of additives found in a tobacco product component
• Modifications that are *not appropriate* for Exemption Requests:
  
  – Product design modifications
  
  – Modification would be expected to change product performance characteristics between new and original tobacco products and not limited to an additive change

  – Tobacco blend modifications

  – **Significant** packaging changes that would effect the characteristics of the tobacco product
REASONS FOR A REFUSE TO ACCEPT (RTA) LETTER

• Modifications are not limited to changes in additives (e.g., tobacco blend changes)

• Failure to submit Exemption Request in an electronic format unless granted permission by FDA

• Failure to provide key information including the following:
  – Environmental assessment (EA)
  – Purpose of the modification
  – Information indicating whether modification is an increase/decrease of existing additive(s) or adding/deleting an additive(s)
  – Information demonstrating original product eligibility as a legally marketed product
  – Full identification of the new and original tobacco product
  – Explanation why modification is minor and why an SE Report is not necessary
• Applications have improved in recent years as applicants have gotten more experience
  – Better organized
  – Clearer link between information and regulatory requirements (e.g., purpose of modification)
  – Improved explanation of why modifications are minor and why a SE Report is not necessary to ensure the protection of public health

• FDA has improved in ability to meet performance goals
  – Welcome feedback on areas where further improvements can be made