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.

FINAL RULE FOR EXEMPTION REQUESTS

- 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

USEFUL INFORMATION TO FACILITATE EXEMPTION REQUESTS REVIEW

- 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

	New Product	Original Product
Tobacco Product Name	Cigarette A	Cigarette B
Tobacco Product Category	Cigarette	Cigarette
Tobacco Product Subcategory	Combusted Filtered	Combusted Filtered
Package Type	Box	Box
Package Quantity	20 cigarettes	20 cigarettes
Length	84 mm	84 mm
Diameter	7.9 mm	7.9 mm
Ventilation	10%	10%
Characterizing Flavor	None	Menthol

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

EXAMPLES OF A MINOR MODIFICATION STATEMENT AND PURPOSE

- 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

POSSIBLE EXEMPTION REQUEST MODIFICATIONS

- 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

INAPPROPRIATE EXEMPTION REQUEST MODIFICATIONS

- 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

CONCLUSION

- 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