EXEMPTION REQUESTS

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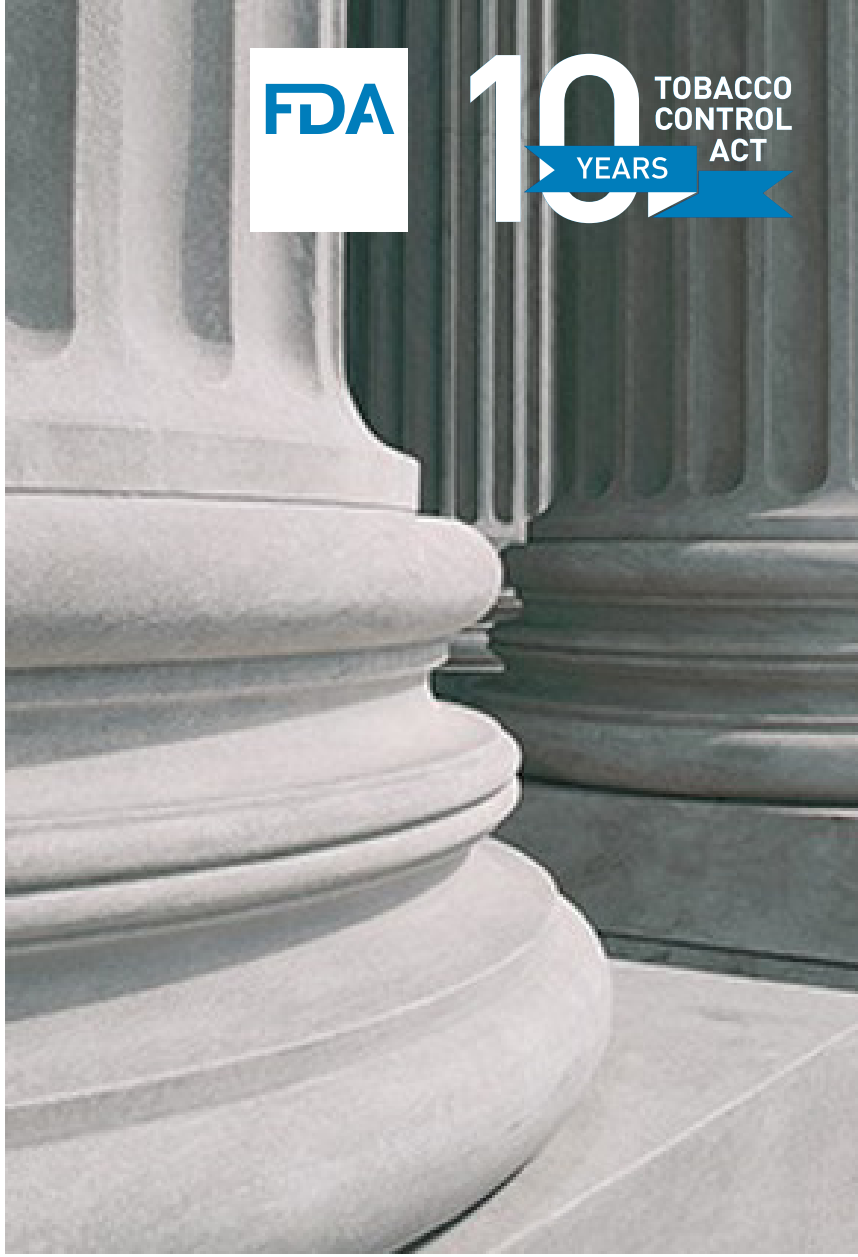


AGENDA

- FDA's Statutory and Regulatory Authority for the Exemption Request Pathway
- Eligibility Requirements for the Exemptions Request Pathway
- Overview of Process and Timeline
- Explanation of differences between an Exemption Request and an SE Report
- Content of an Exemption Request
- Exemption Request Metrics

FDA'S STATUTORY AND REGULATORY AUTHORITY FOR THE EXEMPTION REQUEST PATHWAY

STATUTORY AND REGULATORY AUTHORITY FOR THE EXEMPTION REQUEST PATHWAY

- Statutory Authority:
  - Section 905(j)(3)(A) of the FD&C Act

- Regulatory Authority:
  - Exemption Rule under 21 CFR 1107.1
    - Rule became effective on August 4, 2011
    - EX REQs only marketing pathway with rule in place
  - Refuse to Accept (RTA) Rule under 21 CFR 1105.10
    - Rule became effective on January 30, 2017
    - Applicable to all tobacco product applications: PMTA, MRTPA, SE Reports, and EX REQs

ELIGIBILITY REQUIREMENTS FOR THE EXEMPTION REQUEST PATHWAY

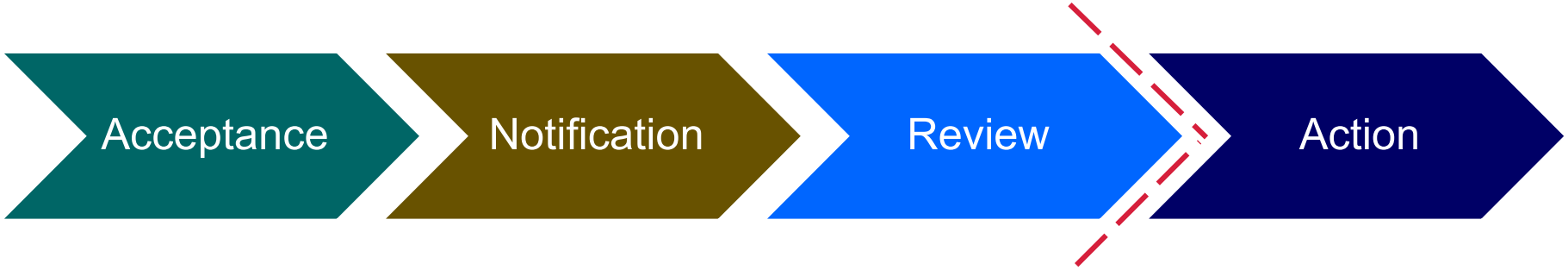
ELIGIBILITY REQUIREMENTS FOR THE EXEMPTION REQUEST PATHWAY

- This pathway may be appropriate if manufacturers can demonstrate:
  - The new tobacco product is modified by adding or deleting a tobacco additive or increasing or decreasing the quantity of an existing tobacco additive
  - The proposed modification is minor and to a legally marketed tobacco product
  - An SE Report is not necessary
  - An exemption is otherwise appropriate

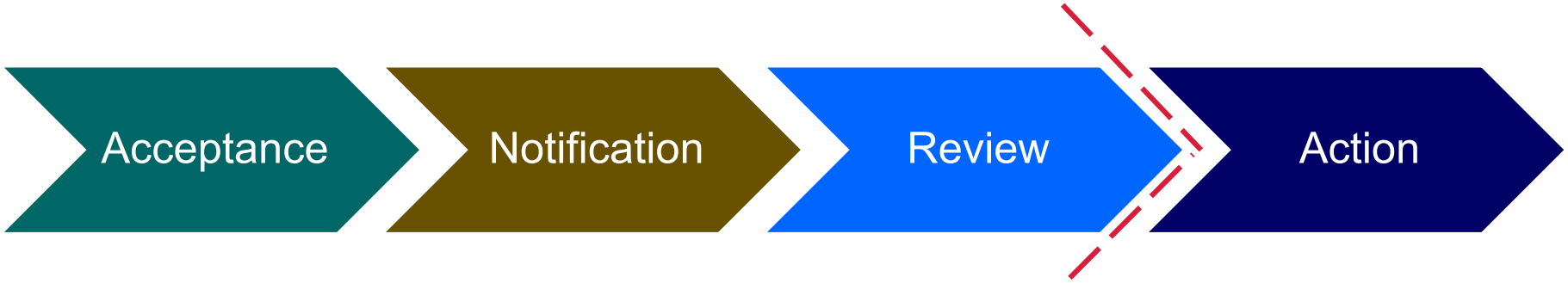
OVERVIEW OF REVIEW PROCESS AND TIMELINE- EXEMPTION REQUESTS

OVERVIEW OF REVIEW PROCESS AND TIMELINE

First Step: Exemption Request



Second Step: Abbreviated Report



ACCEPTANCE CRITERIA FOR ALL MARKETING PATHWAYS

- In accordance with 21 CFR, 1105.10, FDA will refuse to accept an application for review (PMTA, MRTPA, SE or EX), if any of the following apply:

1) The submission does not pertain to a tobacco product	6) The submission is from a foreign applicant and does not identify an authorized U.S. agent
2) The submission is not in English or does not contain complete English translations	7) The submission does not contain required FDA forms
3) If submitted electronically, the submission is in a format FDA cannot process, read, review, and archive	8) The type of submission is not identified
4) The submission does not contain contact information, including applicant's name and address	9) The submission does not contain a signature of a responsible official
5) The submission does not contain product identifying information	10) For all submission types (excluding abbreviated reports), the submission does not include a valid claim of categorical exclusion or an environmental assessment

EXEMPTION REQUEST ACCEPTANCE CRITERIA

- FDA may RTA an Exemption Request application if the following criteria under 21 CFR 1107.1 (b) (1-9) are not met:

APPLICATION FORMAT	PRODUCT INFORMATION	APPLICATION CONTENT
Application is legible	The product can be legally marketed	Manufacturer's contact information
Submitted to FDA in an electronic format*	Proposed modifications are to tobacco additives	Rationale: purpose of the modification, description of the modification, why the modification is minor, and why an SE report is not necessary
	The applicant is the manufacturer	Certification Statement
		EA in accordance with 21 CFR 25.40

*Electronic format or approved alternative format

COMMON CRITERIA MISSING FOR ACCEPTANCE

- Most common criteria missing for the acceptance of an Exemption Request:
  - Submitted in a non-electronic format (such as paper)
  - Tobacco product identification missing (e.g., product category and subcategory, package type, package quantity, or characterizing flavor)
  - Environmental Assessment not included in submission or not in accordance with 21 CFR 25.40

OVERVIEW OF REVIEW PROCESS AND TIMELINE-ABBREVIATED REPORTS

ABBREVIATED REPORTS

- An abbreviated report is the second step for a manufacturer to market the modified tobacco product
- If FDA issues a Found Exempt Order letter for the new tobacco product, Section 905(j)(1)(A)(ii) requires that at least 90 days before introduction or delivery for introduction of the modified tobacco product, manufacturers shall submit a report (referred to as the Abbreviated Report)
  - The manufacturer submits their abbreviated report which should include information demonstrating the following, in accordance with 905(j)(1)(A)(ii):
    - The product is in compliance with the act
    - All modifications are covered by exemptions granted by FDA (Found Exempt Order letter issued)
    - The modifications are to a product that is commercially marketed
    - Actions taken by the manufacturer to comply with the requirements under Section 907, as applicable

ABBREVIATED REPORTS-ACCEPTANCE, REVIEW, AND ACTION

- Acknowledgment
  - FDA intends to issue an acknowledgment letter to the manufacturer
  - This letter acknowledges receipt so that manufacturers are aware of the 90-day timeline that must elapse prior to marketing

- Review
  - During the 90-days, prior to marketing, FDA conducts a review of the abbreviated report
  - FDA will contact the manufacturer if additional information is required

- Action
  - If no additional correspondence from FDA by day 90, the manufacturer may market the new tobacco product within the United States

DIFFERENCES BETWEEN AN EX REQ AND AN SE REPORT

DIFFERENCES BETWEEN SE REPORTS AND EXEMPTION REQUESTS

- Key differences between an SE Report and an Exemption Request:

SE Report	Exemption Request
Compares a new product to a predicate product	Request to modify an original tobacco product
Applicant can utilize any tobacco product for a predicate, whether they manufacture or own the product	Applicant must be the manufacturer of the original product and the new product
Applicants can only use predicate tobacco products which are: grandfathered, have provisional SE status, or have been previously found SE	Applicants can request to modify a legally marketed tobacco product, which includes: grandfathered, provisional SE status, previously found PMTA, SE, or EX

CONTENT FOR EXEMPTION REQUESTS TO FACILITATE FDA REVIEW

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 REQUEST REVIEW

- 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
  - Information to ensure that a previously found SE or previously found EX used as an original tobacco product in a new EX Request are the same/identical product

EXAMPLE OF UNIQUE IDENTIFICATION INFORMATION

	New Product	Original Product
Tobacco Product Manufacturer	Cigar Company 123	Cigar Company 123
Tobacco Product Name	Cigar A	Cigar B
Tobacco Product Category	Cigar	Cigar
Tobacco Product Subcategory	Filtered, Sheet-Wrapped	Filtered, Sheet-Wrapped
Package Type	Box	Box
Package Quantity	5 cigars	5 cigars
Characterizing Flavor	Cherry	Cherry
Length	127 mm	127 mm
Diameter	9.6 mm	9.6 mm
Ventilation	10%	10%
Tip	Plastic Tip	Plastic Tip

Unique ID Memo: https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/scientific-policy-memoranda-about-fda-review-tobacco-product-applications?utm_source=CTPTwitter&utm_medium=social&utm_campaign=ctp-pmta

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 an 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

IS THE MODIFICATION MINOR?

- Questions to consider:
  - Does the additive change impact product performance or HPHCs?
  - Did you modify your tobacco blend?
  - Did you describe the modification in detail?
    - The location within the product
    - Changes to ingredients/additives expressed in absolute quantities (not as percentage)
    - Applicable data to support the modification (e.g., Certificate of Analysis)
    - If supplier of additive changed, were the following provided:
      - Identification of the original and new supplier
      - Statement of what is identical
      - Comparison of differences

IS THE MODIFICATION MINOR?

- Modifications which *may be* considered minor under an Exemption Request:
  - Change in additive 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 container closure system 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 (e.g., adhesives)

IS THE MODIFICATION MINOR?

- Modifications which may not be considered minor for Exemption Requests:
  - Product design modifications which would be expected to change product performance characteristics between new and original tobacco products and/or not limited to an additive change
  - Tobacco blend modifications (e.g., grade, quantity, type)
  - Container closure changes that would effect the characteristics of the tobacco product
  - Collective modifications of a tobacco product are not minor even if individual modifications may be minor

EXEMPTION REQUEST METRICS

EX APPLICATIONS BY PRODUCT CATEGORY: STATUTORILY REGULATED PRODUCTS

	Received FY 19	Open FY 19	Closed* FY 19			
			EX	NEX	RTA	Withdrawn
Cigarettes	338	85	210	8	18	17
Roll Your Own	4	0	2	0	2	0
Smokeless	5	0	3	1	0	1
Total	347	85	262			

* Closed means CTP has taken an action on an application. Closed includes refuse-to-accept, refusal-to-file, withdrawn, closure due to administrative issues, environmental information request letter, predicate advice letter, removed from review, or issuance of order letter as applicable to each program.

EX APPLICATIONS BY PRODUCT CATEGORY: STATUTORILY REGULATED PRODUCTS CUMULATIVE TOTAL

	Received	Open	Closed*			
			EX	NEX	RTA	Withdrawn
Cigarettes	482	85	302	10	42	43
Roll Your Own	11	0	2	0	9	0
Smokeless	55	2	4	12	25	12
Total	548	87	461			

*Closed means CTP has taken an action on an application. Closed includes refuse-to-accept, refusal-to-file, withdrawn, closure due to administrative issues, environmental information request letter, predicate advice letter, removed from review, or issuance of order letter as applicable to each program.

EX APPLICATIONS BY PRODUCT CATEGORY: DEEMED PRODUCTS

	Received FY 19	Open FY 19	Closed* FY 19			
			EX	NEX	RTA	Withdrawn
Cigars	19	0	19	0	0	0
Pipe	0	0	0	0	0	0
Water Pipe	0	0	0	0	0	0
ENDS	0	0	0	0	0	0
Other	0	0	0	0	0	0
Total	19	0	19			

**Closed means CTP has taken an action on an application. Closed includes refuse-to-accept, refusal-to-file, withdrawn, closure due to administrative issues, environmental information request letter, predicate advice letter, removed from review, or issuance of order letter as applicable to each program.

EX APPLICATIONS BY PRODUCT CATEGORY: DEEMED PRODUCTS CUMULATIVE TOTAL

	Received	Open	Closed*			
			EX	NEX	RTA	Withdrawn
Cigars	21	0	21	0	0	0
Pipe	0	0	0	0	0	0
Water Pipe	0	0	0	0	0	0
ENDS	0	0	0	0	0	0
Other	0	0	0	0	0	0
Total	21	0	21			

*Closed means CTP has taken an action on an application. Closed includes refuse-to-accept, refusal-to-file, withdrawn, closure due to administrative issues, environmental information request letter, predicate advice letter, removed from review, or issuance of order letter as applicable to each program.

THE END