REQUEST FOR EXEMPTION FROM SUBSTANTIAL EQUIVALENCE (EXEMPTION REQUEST, EX REQ)

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AGENDA

- Introduction of Tobacco Product Marketing Pathways
- FDA's Statutory and Regulatory Authority for the Exemption Request pathway
- Eligibility for EX REQ Pathway
- Overview of Processes and Timelines
- Program updates

INTRODUCTION OF TOBACCO PRODUCT MARKETING PATHWAYS

MARKETING PATHWAYS FOR NEW TOBACCO PRODUCTS

- There are three pathways available to bring a new tobacco product to market in the United States:
  - Premarket Tobacco Product Applications (PMTA)
  - Substantial Equivalence (SE) Applications
  - Requests for Exemption from Substantial Equivalence (EX REQ)

- The Exemption Request process requires the completion of two steps in order to market a modified tobacco product:
  - Step One: Receipt of an Exempt Order
  - Step Two: Submission of an Abbreviated Report

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

STATUTORY AND REGULATORY AUTHORITY

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

- Regulatory Authority:
  - Exemption Rule under 21 CFR 1107.1(b)
    - 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, Modified Risk Tobacco Product Applications (MRTPA), SE Applications, and EX REQs

ELIGIBILITY FOR EX REQ PATHWAY

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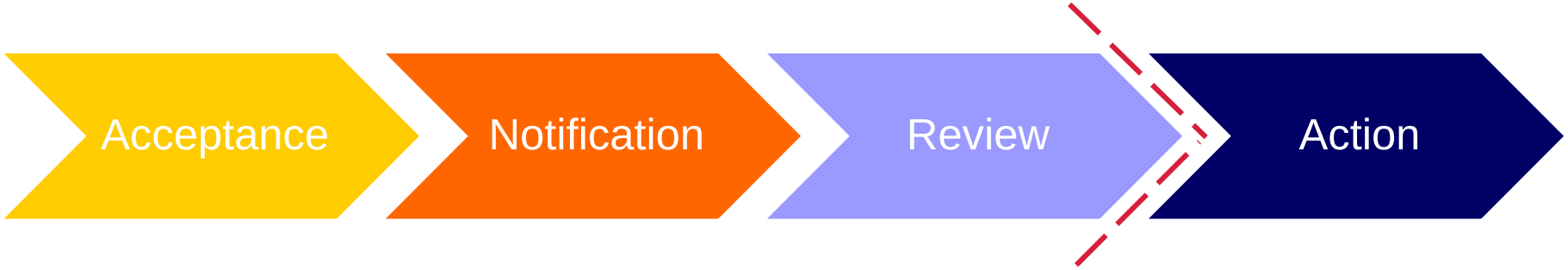
- This pathway may be appropriate if manufacturers can demonstrate:
  - The new tobacco product is modified by adding or deleting a tobacco additive or increasing or decreasing the quantity of an existing tobacco additive
  - The proposed modification is minor and to a legally marketed tobacco product
  - An SE Report is not necessary
  - An exemption is otherwise appropriate
- An interactive tool to assist manufacturers in determining the most appropriate pathway to use for their product is available on the FDA website

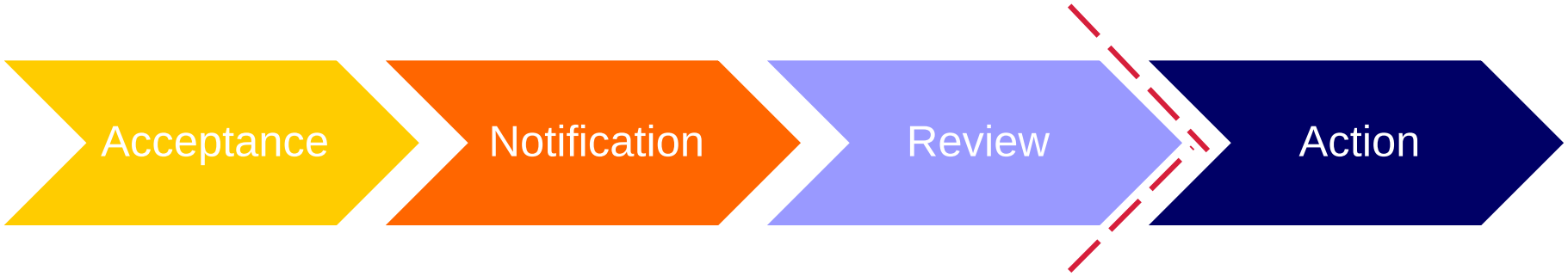
OVERVIEW OF PROCESS AND TIMELINE

EXEMPTION REQUEST REVIEW PROCESS

First Step: Exemption Request



Second Step: Abbreviated Report



EXEMPTION REQUEST ACCEPTANCE CRITERIA

- FDA may RTA an EX 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	Regulated under Chapter IX of the FD&C Act	Manufacturer's contact information
Application is in English or an English translation is provided	The product is legally marketed	Rationale: purpose of the modification, why the modification is minor, and why an SE report is not necessary
Submitted to FDA in an electronic format*	Proposed modifications are to tobacco additives	Certification Statement
	The applicant is the manufacturer	EA in accordance with 21 CFR 25.40
	Full Identification of the product	

Acceptance

*Electronic format or approved alternative format

ACCEPTANCE CRITERIA FOR ALL MARKETING PATHWAYS

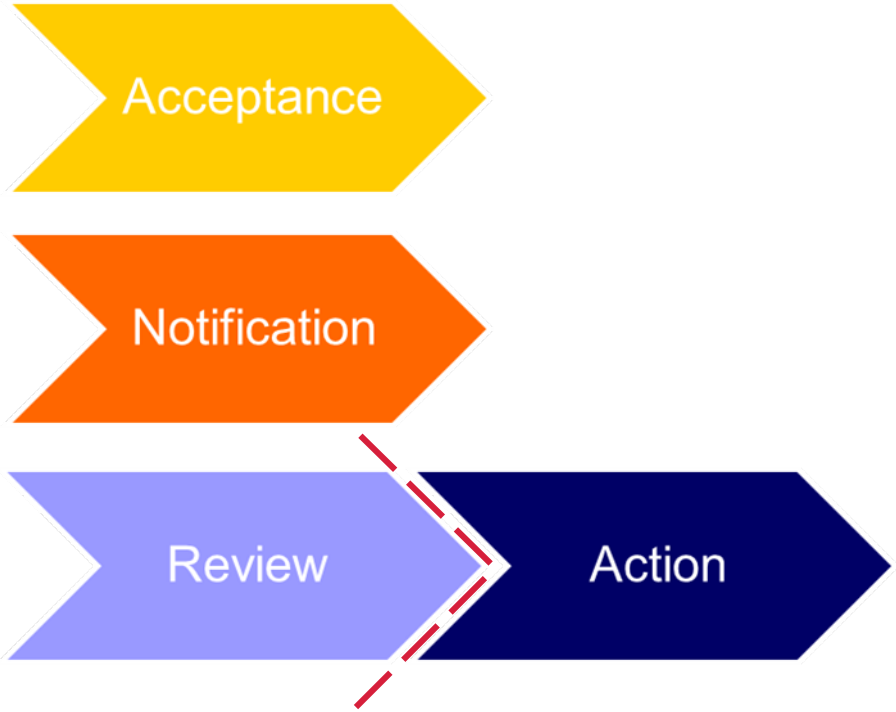
- In accordance with 21 CFR, 1105.10, FDA will refuse to accept an application for review (PMTA, MRTPA, SE or EX), if any of the following apply:

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

Acceptance

EXEMPTION REQUEST REVIEW PROCESS

- Steps in the Exemption Request review process:
  1. Submission and receipt of application
  2. Acceptance determination
     a. Accept and continue review; or
     b. RTA the application
  3. Notification
  4. Review and Action



EXEMPTION REQUEST REVIEW PROCESS-NOTIFICATION

- The Notification phase consists of the following steps:
  1. When a manufacturer proposes to modify an original tobacco product legally marketed under a pending provisional SE Report they will receive a notification letter from FDA.
  2. The letter notifies the manufacturer that FDA will first review the pending provisional SE Report and once a final determination of the SE Report is issued, FDA will begin review of the EX Request.

EXEMPTION REQUEST REVIEW PROCESS-REVIEW

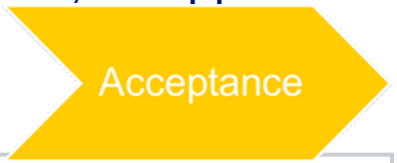
- Substantive Scientific Review
  - During review, FDA may issue an Advice/Information Request (A/I) Letter to request additional information to complete scientific review of the application
    1) If the manufacturer provides a response by the date requested in the A/I letter, FDA continues review of the EX Request
    2) If a response is not received by the date requested in the A/I letter FDA considers the EX REQ(s) withdrawn

EXEMPTION REQUEST REVIEW PROCESS-ACTION

- Action
  - Once FDA has completed substantive scientific review, one of the following letters is issued to the manufacturer with FDA's findings:
    1) A/I
    2) Cancellation or Closure
    3) Exempt
    4) Not Exempt

EXEMPTION REQUEST REVIEW PROCESS-ABBREVIATED REPORTS-ACCEPTANCE

- 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



EXEMPTION REQUEST REVIEW PROCESS-ABBREVIATED REPORTS-NOTIFICATION

- 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

EXEMPTION REQUEST REVIEW PROCESS-ABBREVIATED REPORTS-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

EXEMPTION REQUEST REVIEW PROCESS-ABBREVIATED REPORTS-ACTION

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

PROGRAM UPDATES

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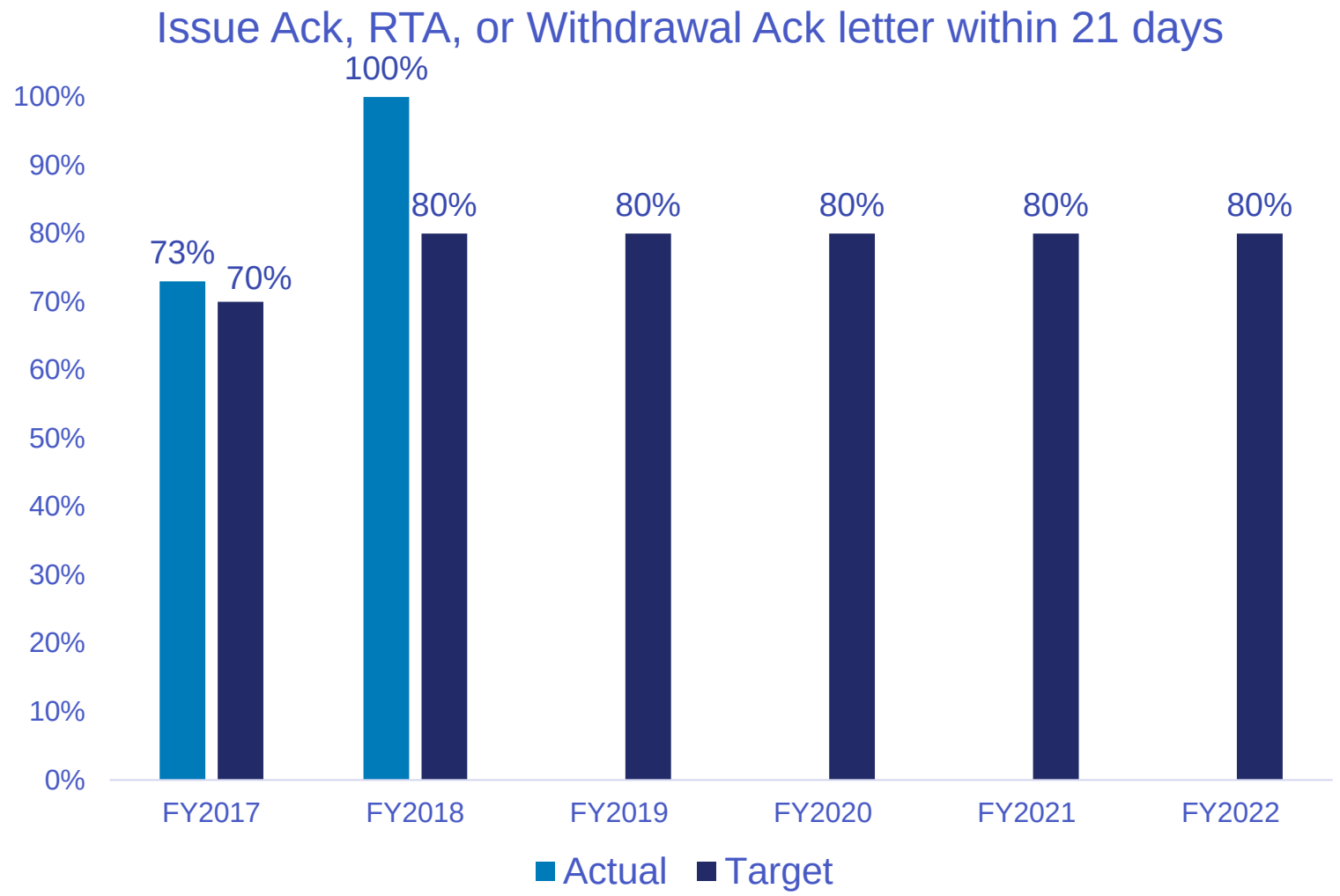
- FDA established performance measures and timeframes for review of EX REQs
  - FDA performance goals for EX Requests:
    - Within **21 days** FDA intends to issue one of the following letters:
      - Acknowledgement, Refuse to Accept, or Withdrawal Acknowledgement
    - Within **60 days** of receipt of application or response to A/I letter, FDA intends to review and act on an EX Request, by issuing one of the following letters:
      - A/I letter, Cancellation letter, Closure letter, an Exempt order letter, or a Not Exempt order letter

PERFORMANCE GOALS



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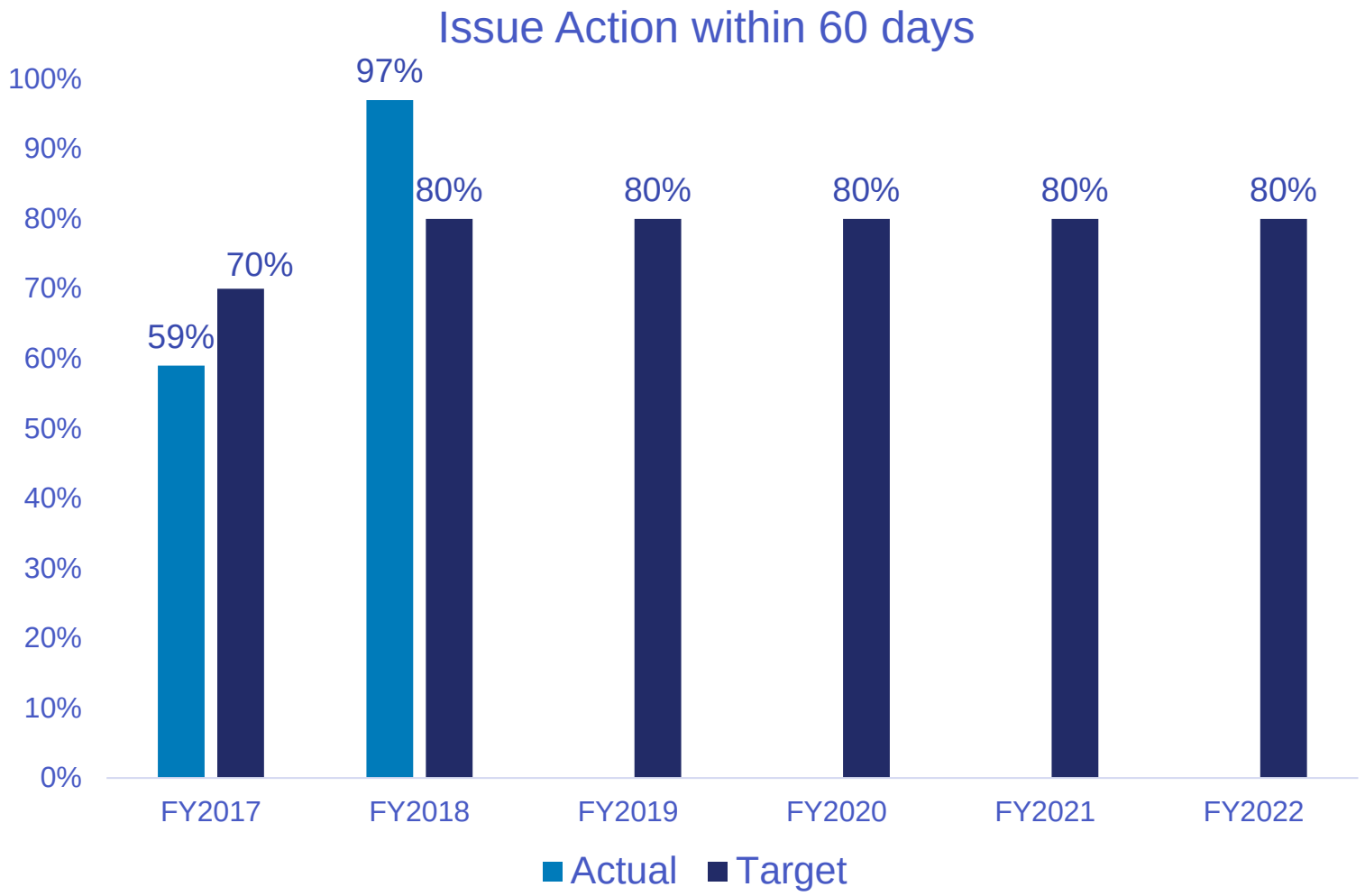

FY2017: Correction to Value on FDA Website

FY2018: Cohort is open

PROGRAM UPDATES

- Abbreviated Report Submissions
  - The Exempt Order letter includes FDA's suggested format for the submission of the Abbreviated Report
  - Manufacturers may use this format to certify that the tobacco product has met the requirements in sections 905(j)(1)(A)(ii) and 905(j)(1)(b) of the FD&C Act

PROGRAM UPDATES

- Environmental Assessment Considerations
  - For Exemption Requests, 21 CFR 1107.1(b)(9) states that an exemption request must contain, “An environmental assessment under part 25 of this chapter prepared in accordance with the requirements of §25.40 of this chapter”
  - FDA previously refused to accept Exemption Requests that did not include the basic elements required for a complete EA
  - However, as industry is still gaining experience with developing EAs, FDA will accept Exemption Requests that include an EA. An A/I letter may contain additional information needed for the EA

THE END