CTP'S AUTHORITY IN REVIEWING TOBACCO PRODUCT MARKET APPLICATIONS

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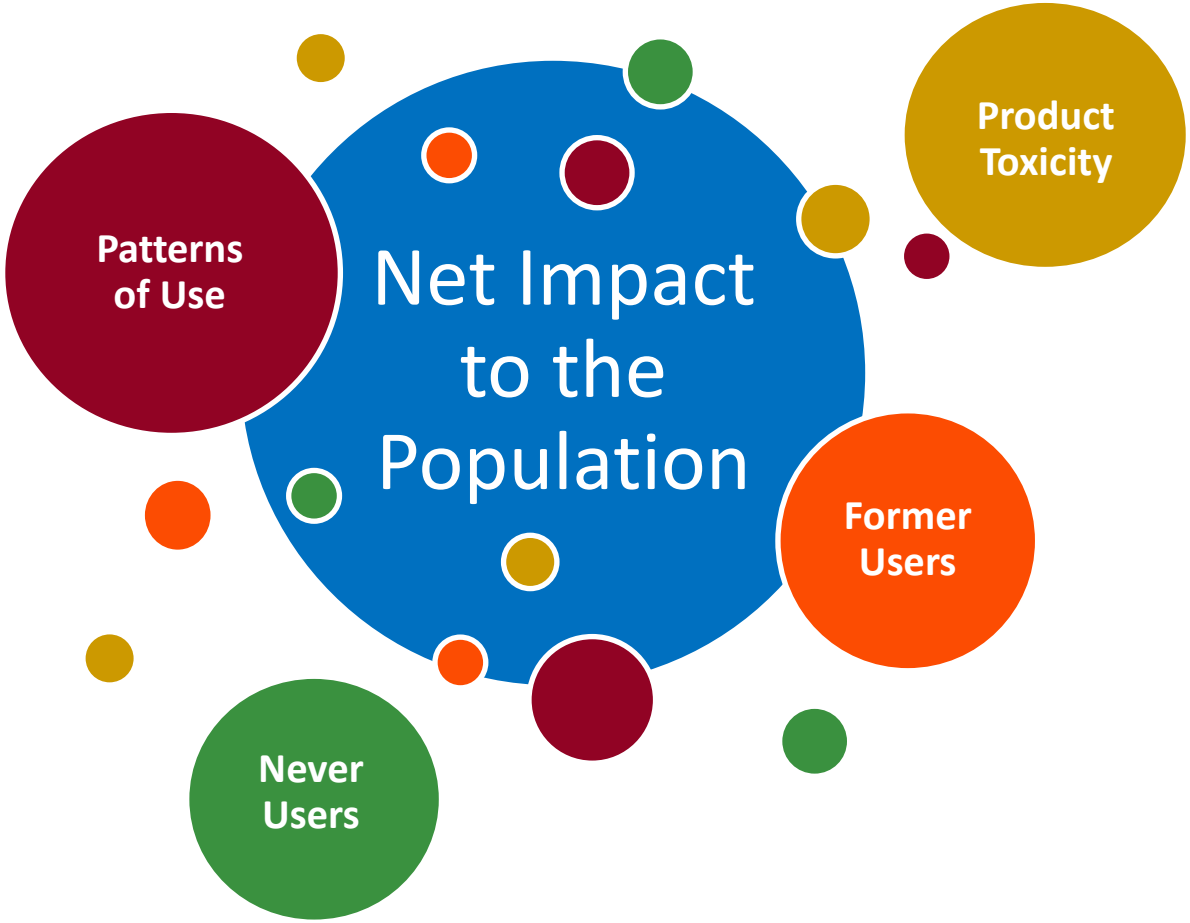
PRODUCT REVIEW

- Application types
  - Exemption Request (EX REQ)
  - Substantial Equivalence Report (SE Report)
  - Pre-Market Tobacco Product Application (PMTA)
  - Modified Risk Tobacco Product Application (MRTPA)
- Pre-market review decisions are based on the best available science
- Applicant must provide adequate evidence for FDA to make a finding
- FDA uses scientific research to evaluate the evidence provided by the applicant

ASSESSING OVERALL IMPACT TO PUBLIC HEALTH



TOBACCO PRODUCT MARKETING PATHWAYS

Tobacco Product Introduced to Market	Defined as	Submission to FDA	Continue to Market or Start Marketing?
As of Feb. 15, 2007 (no changes)	"Grandfathered"	None	
Feb. 16, 2007 – March 21, 2011	"New Tobacco Product," but "Provisional Tobacco Product"	SE Report*	
Feb. 16, 2007 – present	"New Tobacco Product"	PMTA, SE Report, or EX REQ	

*submitted by March 22, 2011

MRTPA SCENARIOS

Scenario	Submission to FDA	Needed to Market the Modified Risk Tobacco Product
MRTPA for Grandfathered Product	MRTPA	1 order: MRTP order
MRTPA for Provisional Tobacco Product	MRTPA & SE Report*	1 order: MRTP order but no NSE order
MRTPA for New Tobacco Product	MRTPA & PMTA, SE Report, or EX REQ	2 orders: MRTP order & marketing order

*submitted by March 22, 2011

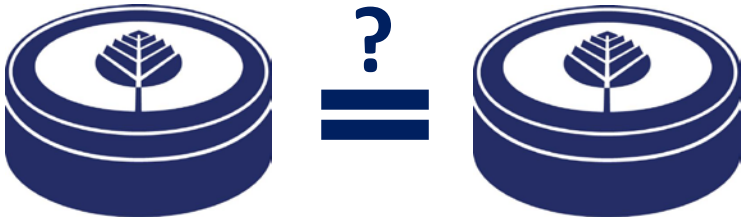
SUBSTANTIAL EQUIVALENCE REPORT (SE REPORT)

- Substantial equivalence = comparison of new and predicate product characteristics

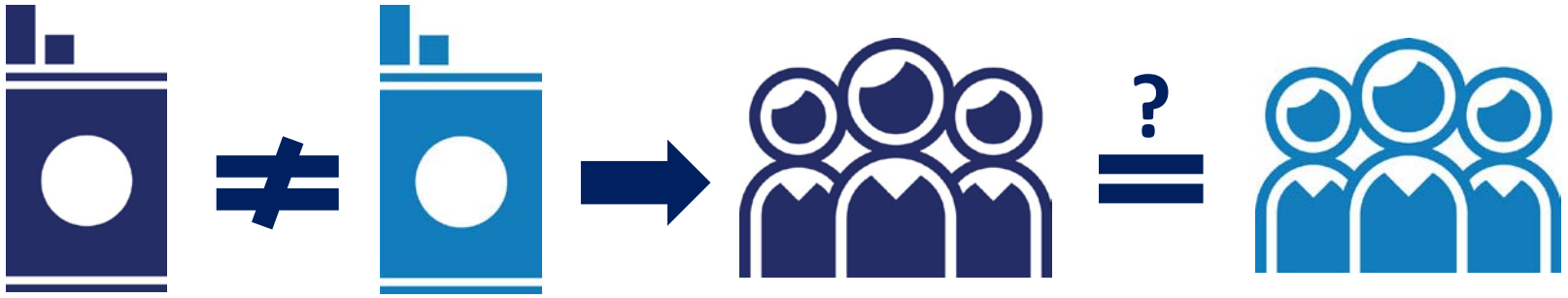
- Characteristics of new and predicate products in application
  - Design Features
  - Ingredients
  - Materials
  - Heating Source
  - Composition
  - Other Features

SE REPORT:
STANDARD FOR MARKETING ORDER

- Does the new product have the same characteristics as a predicate product?



- If the characteristics are different, do the changes raise different questions of public health?



EXEMPTION REQUEST (EX REQ)

- EX REQ = comparison of new and original products

- Exempt from demonstrating substantial equivalence if
  - Only change is to an additive
  - Change is minor
  - Full SE Report is not necessary to ensure that permitting the tobacco products to be marketed is appropriate for the protection of public health
  - An exemption is otherwise appropriate

PRE-MARKET TOBACCO APPLICATION (PMTA)

- Application content
  - Full reports of investigations of health risks
  - All components, ingredients, additives, properties, and principles of operation
  - Methods of manufacturing and processing
  - Compliance with tobacco product standards
  - Product samples and components (if reasonably required)
  - Proposed labeling

- Standard for marketing order
  - Would permitting such a product to be the marketed be appropriate for the protection of public health?

PMTA: APPROPRIATE FOR THE PROTECTION OF PUBLIC HEALTH

- The risks and benefits to the population as a whole including users and nonusers of tobacco products
- Likelihood of impact on cessation
- Likelihood of impact on initiation

MODIFIED RISK TOBACCO PRODUCT APPLICATION (MRTPA)

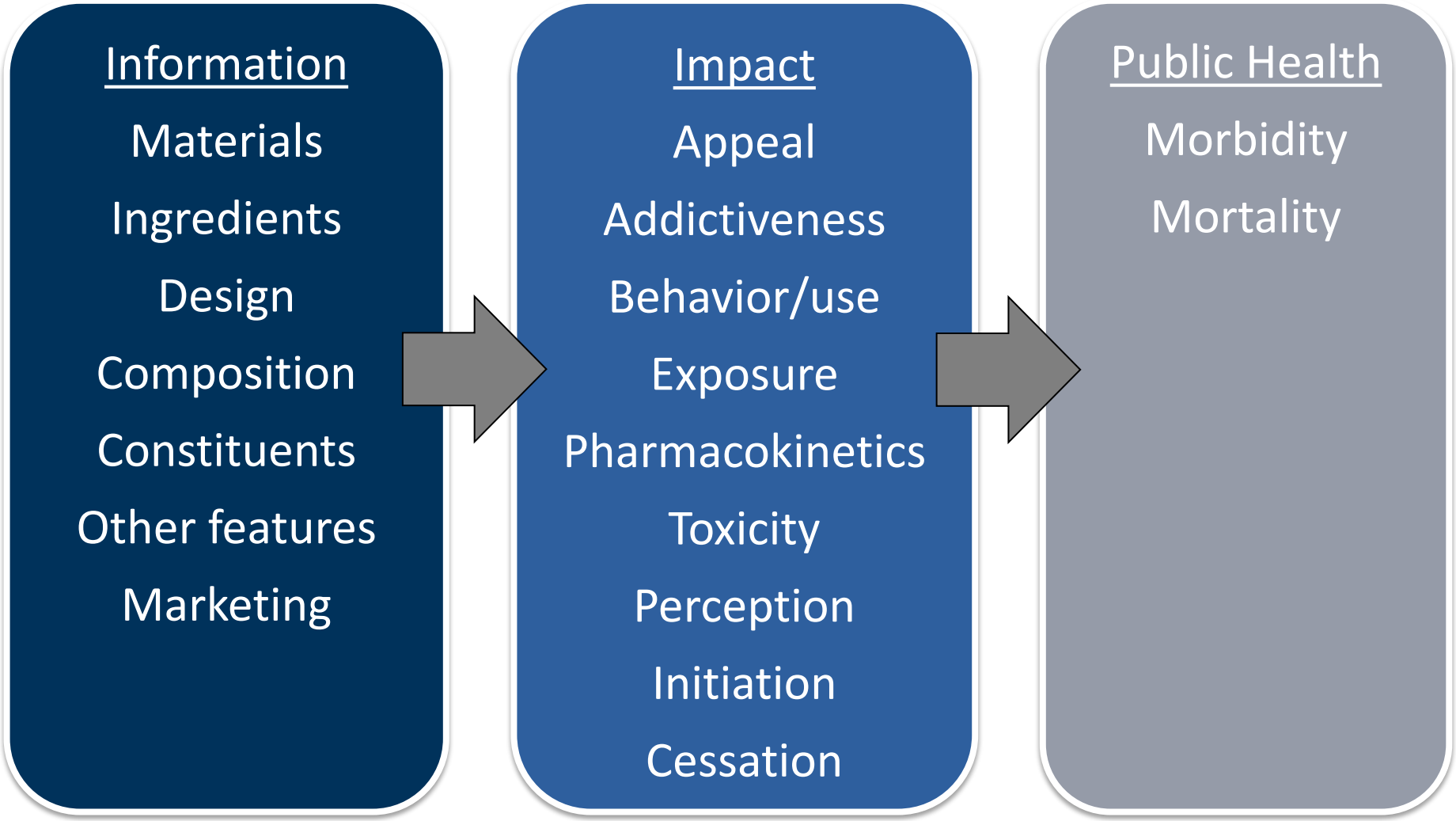
- Not application to get product on market
  - Application to market a product as for use to reduce harm or the risk of tobacco-related disease

- Two types of orders:
  - Risk modification order
  - Exposure modification order

Application content

- Description of the product and proposed advertising and labeling
- Conditions for using the product
- Formulation of the product
- Sample product labels and labeling
- All documents related to research findings
- Data and information on how consumers actually use the product

PRODUCT REVIEW CONSIDERATIONS



CONCLUSION

There are different statutory standards for each marketing pathway, but…

CTP's goal is to protect the public health