CONSUMER UNDERSTANDING IN MODIFIED RISK TOBACCO PRODUCT APPLICATIONS

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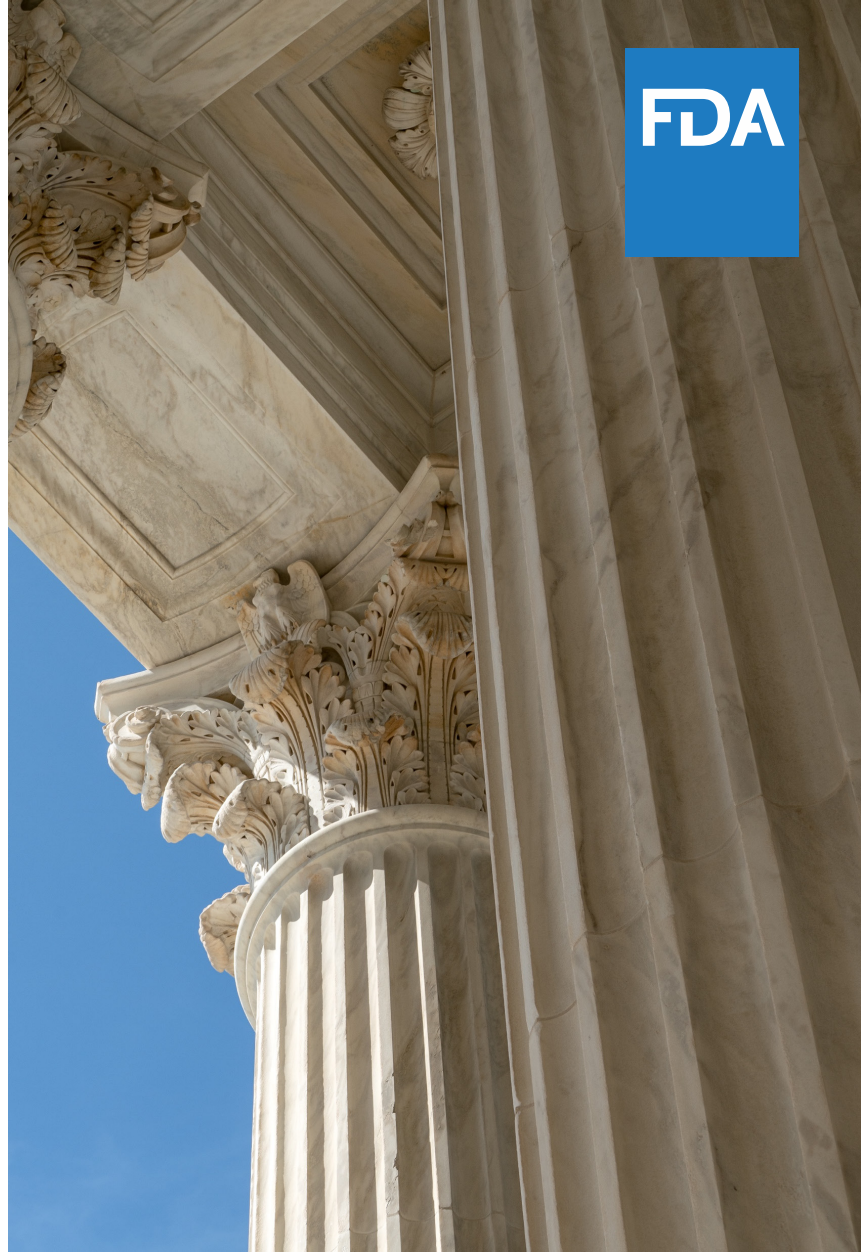

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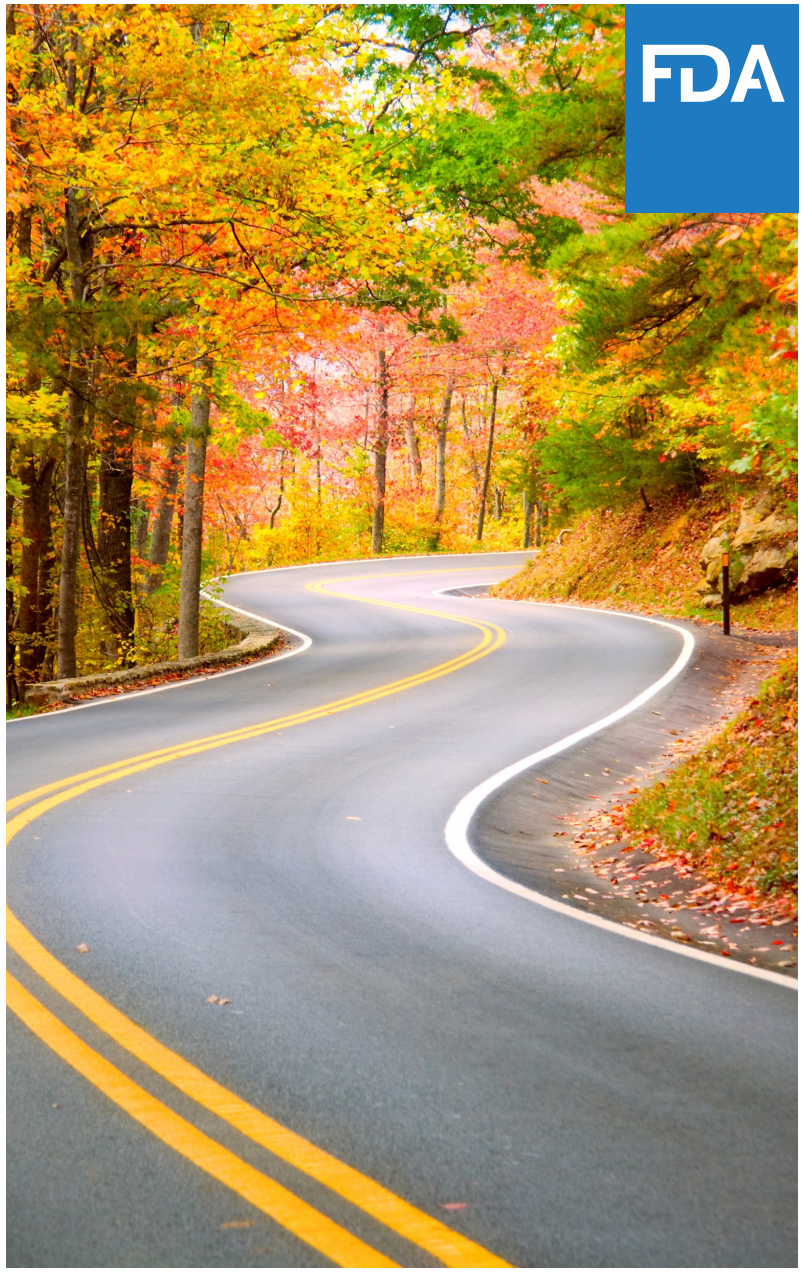
AGENDA

1. Background and Regulatory Standard
2. Modified Risk Labels, Labeling, and Advertising
3. Potential Framework for Assessing Consumer Understanding of MRTPs
4. Assessing Understanding: Relevant Constructs
5. Measurement Considerations
6. Questions for the Committee



BACKGROUND AND REGULATORY STANDARD

FDA SCIENTIFIC REVIEW OF MRTPAS

- Scientific review includes the following key areas of focus:
  - Product description and characterization
  - Identification of modified risk information
  - Substantiation of modified risk information
  - Relative health risks to individuals
  - Consumer understanding and perception*
  - Impact to the population as a whole
  - Environmental review and National Environmental Protection Act (NEPA)
- Reviews are based on all available scientific evidence related to the product — both the information provided by the applicant and any other relevant information available to the Agency, including from the general scientific literature.

* Focus of today's presentation

BACKGROUND: THE NEED FOR THE MRTP PATHWAY

Congress found that marketing modified risk tobacco products could present risks to the public, including:

- Young people, including minors
- People who currently use tobacco

Congress also found that the public may misunderstand such marketing.

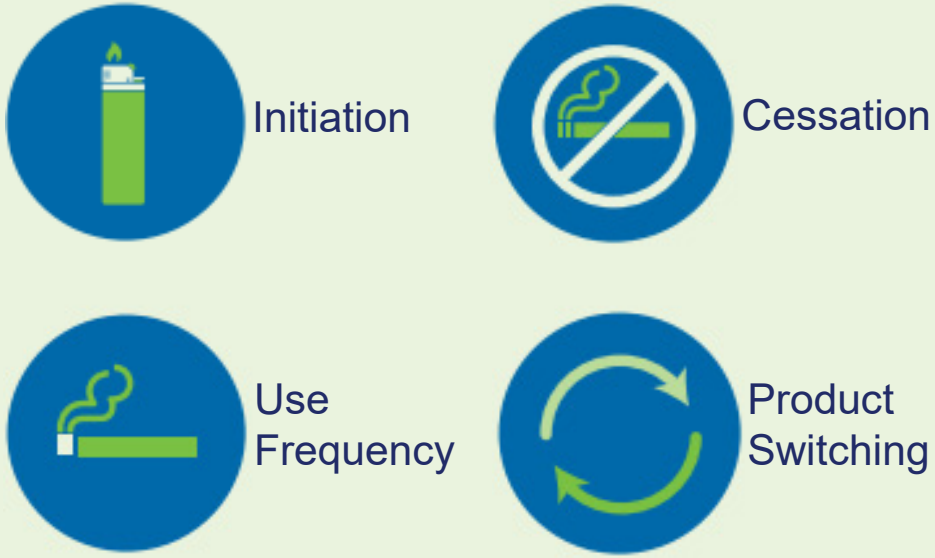
The FD&C Act States:

> The Secretary shall require for the marketing of a product under this section that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products.

CONSUMER UNDERSTANDING

As a statutory mandate, applicants must demonstrate adequate consumer understanding (FD&C Act, Section 911(h)(1)).

Understanding of risk information can affect tobacco use[1-9]



[1] Arnett. *Addict Behav* 2000; 25(4):625-632.
[2] Borrelli et al. *Addiction* 2010; 105(6): 1100-1108.
[3] Costello et al. *Am J Health Behav* 2012; 36(5): 681-692.
[4] DiFranza et al. *Tob Control* 2012; 21:471-476
[5] Halpern-Felsher et al. *Prev Med* 2004; 39(3):559-567.
[6] Leventhal et al. *JAMA* 1987; 257(24):3373.
[7] Slovic. *Duke Law J* 1998; 47:1133-1141.
[8] Slovic. *Smoking: Risk, perception, & policy*. 2001.
[9] Song et al. *Am J Public Health* 2009; 99(3):487-492.

MODIFIED RISK LABELS, LABELING, AND ADVERTISING (LLA)

WHAT ARE LABELS, LABELING, AND ADVERTISING (LLA)?

Labels

A display of written, printed, or graphic matter upon the immediate container of any article.

Labeling

Labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such article (§ 201(m)).

Advertising

- The FD&C Act does not define what constitutes an advertisement.
- Examples include advertisements in published journals, magazines, other periodicals, newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.

MODIFIED RISK LABELS, LABELING, AND ADVERTISING (LLA) IN MRTPAS

FDA

Modified risk LLA in MRTPAs have typically included information about:

The reduced risk or reduced exposure claim stating that the product is lower risk or has lower exposure than another tobacco product

&

How to use the product to get the risk or exposure reduction (e.g., a description of use patterns or use instructions)

Modified risk LLA in MRTPAs have also included information such as:

General product information, particularly for products that may be unfamiliar to many consumers (e.g., "What is snus?" or "How do I use it?")

"Balancing information"* (e.g., "No tobacco product is safe" or "If you're a smoker concerned about the health risks from smoking, the best choice is to quit.")

"Disclaimers"* (e.g., "Less nicotine does NOT mean safer.")

* FDA has not defined these terms; this is how applicants have frequently used them.

MODIFIED RISK MARKETING AND PROMOTIONS

Modified risk information may be included on:

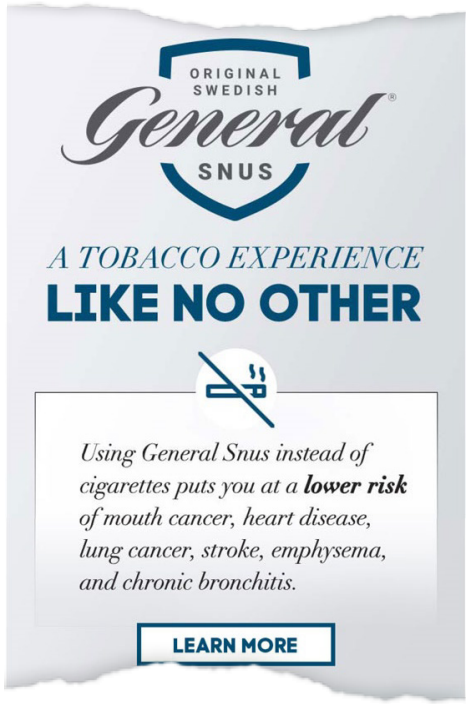
- package labels, inserts, or onserts
- various other materials such as direct mail, email, point-of-sale, print media, digital media

Marketing may be:

- targeted (e.g., limited to materials and locations unlikely to be seen by people under the federal legal age of sale of tobacco products)
- designed to be appealing to specific tobacco user groups and age groups

EXAMPLES FROM SELECTED AUTHORIZED MRTPS

Snippets from an email ad (left) and two print magazine ads (middle and right)*



* Source: Rutgers Institute for Nicotine and Tobacco Studies, Online Surveillance System & Archive of Tobacco Products & Marketing Materials

POTENTIAL FRAMEWORK FOR ASSESSING CONSUMER UNDERSTANDING OF MRTPs

THREE COMPONENTS OF CONSUMER UNDERSTANDING

Would the modified risk LLA enable the public to understand…

… what risk reduction or exposure reduction is described?

… that the proposed MRTP does confer health risks or harm and is more harmful than non-use,cessation?

… how to use the proposed MRTP to reduce one's risk or exposure?

UNDERSTANDING WHAT SPECIFIC RISK REDUCTION OR EXPOSURE REDUCTION IS DESCRIBED

- Would the LLA enable consumers to understand that the MRTP poses less risk of outcome X, is less harmful, or reduces exposures to specific substances relative to the comparator product?
- Example: For LLA with information about reduced risk of diseases A, B, and C, would consumers understand that the product presents lower risk of these diseases than the comparator product?

UNDERSTANDING THAT THE MRTP DOES CONFER HEALTH RISKS AND IS MORE HARMFUL THAN CESSATION

Would the LLA enable consumers to understand:

- the absolute health risks and harms of using the MRTP (including addiction)?
- the health risks and harms relative to ceasing all tobacco use and/or using FDA-approved cessation therapies?

UNDERSTANDING HOW TO USE THE MRTP TO REDUCE ONE'S RISK OR EXPOSURE

- Would the LLA enable consumers to understand how the MRTP is intended to be used to benefit from the risk or exposure reduction?
- For example, consumers may need to completely switch from the comparator product, use the MRTP exclusively, or cut down substantially on one's use of the comparator product. LLA could potentially convey such ideas through phrasing such as "completely switch," "as a complete substitute for," "instead of," "100% of the time," or "exclusive use of." [1-3]

[1] Corporate Research Associates. *Testing of Relative Risk Statements for Vaping Products*; 2018. Available at: https://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2019/014-18-e/report.pdf.
[2] Owusu, Lawley, Yang, Henderson, Bethea, LaRose, Stallworth, & Popova. *Tob Control* 2020; 29(2):217-223.
[3] Yang, Massey, & Popova. *Tob Control* 2022; 31(e1):e41-e49.

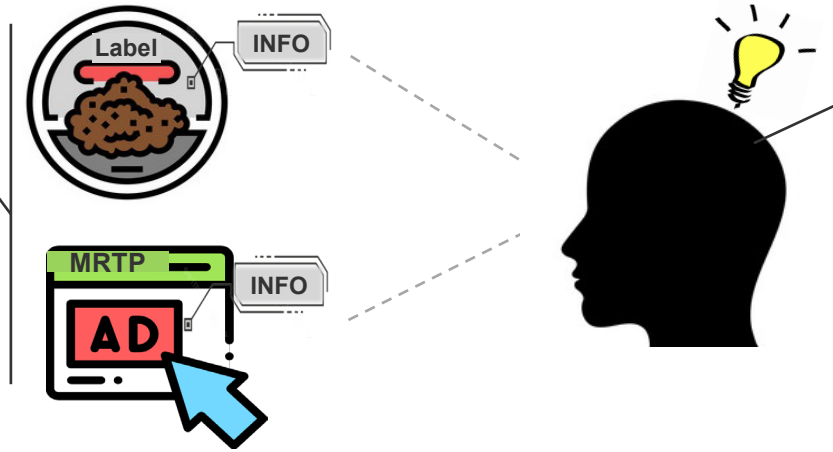
ASSESSING UNDERSTANDING: RELEVANT CONSTRUCTS

OPERATIONALIZING UNDERSTANDING IN MRTPA

- Understanding is multifaceted and can be conceptualized in multiple, overlapping ways.
- In MRTPAs, we are interested in comprehension of risk-related information and understanding the significance of that risk-related information.

Does the modified risk information appear to be:

- Plain language, readable?
- Accurate?
- Not misleading?



After viewing the LLA:

- Can people correctly answer questions about the info and product risks?
- Do people have accurate risk perceptions?

POTENTIAL LINES OF EVIDENCE

Evidence on whether the LLA will enable the public to understand the modified risk information comes from:

- The LLA itself: appearance of understandability
- Tobacco product perception and intention (TPPI) studies
  - Assess, among other things, whether members of the public actually understand the information
  - Conducted by the applicant or by other researchers
  - Submitted in the MRTPA or in public comments, or published in the scientific literature
  - Can include qualitative and quantitative designs
  - Note: FDA published a Guidance for Industry on Principles for Designing and Conducting TPPI Studies*

* TPPI Study Guidance Available at: https://www.fda.gov/media/143322/download

EVIDENCE FROM THE LLA ITSELF

In past reviews we have considered the extent to which the modified risk information would appear to promote the public's understanding of the product's risks.

Examples of factors we have considered are:

- Does the information appear to be accurate and not misleading?
- Does the information appear to be readable, clear, and comprehensible to people even if they do not have a high level of formal education?
- Does the information explicitly describe conditions for use or what one needs to do to reduce their risk or exposure?

EVIDENCE FROM TPPI STUDIES

We consider findings related to consumer understanding from TPPI studies* in which members of the public view the proposed modified risk LLA and subsequently answer questions assessing constructs such as:

* More information available in FDA's Guidance for Industry on Principles for Designing and Conducting TPPI Studies: https://www.fda.gov/media/143322/download

TPPI STUDY CONSTRUCTS: RECOGNITION AND RECALL

- Recognition and recall refer to consumers' ability to remember or identify the modified risk information either while viewing it or after viewing it.
- These reflect surface-level understanding.
- Items typically ask respondents to complete or fill in part of a statement that appears in the modified risk LLA.

Recognition

- Cued or aided (e.g., choosing text from a list that includes the verbatim claim wording).
- Example: *"Based on the ad you just viewed... Nicotine free cigarettes are less harmful than regular cigarettes"* (T/F) [1]

[1] Johnson et al. *Nicotine Tob Res* 2019; 21(S1):S117–S124.

Recall

- Unaided. Open text.
- Example: "*Please write down everything you can remember about the advertisement.*" [2]

[2] Strack et al. *J App Soc Psych* 2008; 38(2):281-93.

TPPI STUDY CONSTRUCTS: KNOWLEDGE

- Knowledge refers to consumers' ability to answer questions about their interpretation of the information on the modified risk LLA.
- Knowledge questions can be quantitative (e.g., multiple-choice) or qualitative (e.g., open-ended survey items; prompts in in-depth interviews or focus groups).
- Knowledge questions can concern information such as the health effects of switching from the comparator product to the proposed MRTP or the manner in which someone would have to use the proposed MRTP to reduce risk or exposure.

Examples:

- *"In the statement above, "switching completely" means…"* (open-ended) [1]
- *"The best choice for my health would be to…" (1) use both [Product] and cigarettes, (2) quit cigarettes and only use [Product], or (3) stop using all tobacco products.*

[1] modified based on McKelvey et al. *Tob Control* 2020; 29: e18-e24.

TPPI STUDY CONSTRUCTS: RISK PERCEPTIONS

FDA

Absolute Risk Perceptions:

Judgments about the absolute likelihood or severity of health risks of using the proposed MRTP (ideally, with a particular frequency and/or duration of use specified)

General: *How much do you think people harm themselves when they use [Product]? (No harm, Little harm, Some harm, A lot of harm, Don't know)*

Specific: *Imagine that you use [Product] daily for the rest of your life. How likely do you think it is that you will get lung cancer in your lifetime? (Not at all likely, A little likely, Somewhat likely, Very likely, Extremely likely, Don't know)* [1]

Relative Risk Perceptions:

Judgments about the health risks of using the proposed MRTP compared to the health risks of using the comparator product, other tobacco products, quitting tobacco, and using cessation aids

General: *Compared to smoking cigarettes, do you think using [Product] is … (1) much less, (2) a little less, (3) equally as, (4) a little more, (5) much more … harmful, or (6) Don't know (DK)?*

Specific: *If you completely switched to [Product] and stopped using cigarettes tomorrow, how would this affect your chances of getting lung cancer? My chances would be (1) much lower, (2) a little lower, (3) about the same, (4) a little higher, (5) much higher, (6) DK*

[1] modified based on McKelvey et al. *Tob Control* 2020; 29: e18-e24.

MEASUREMENT CONSIDERATIONS

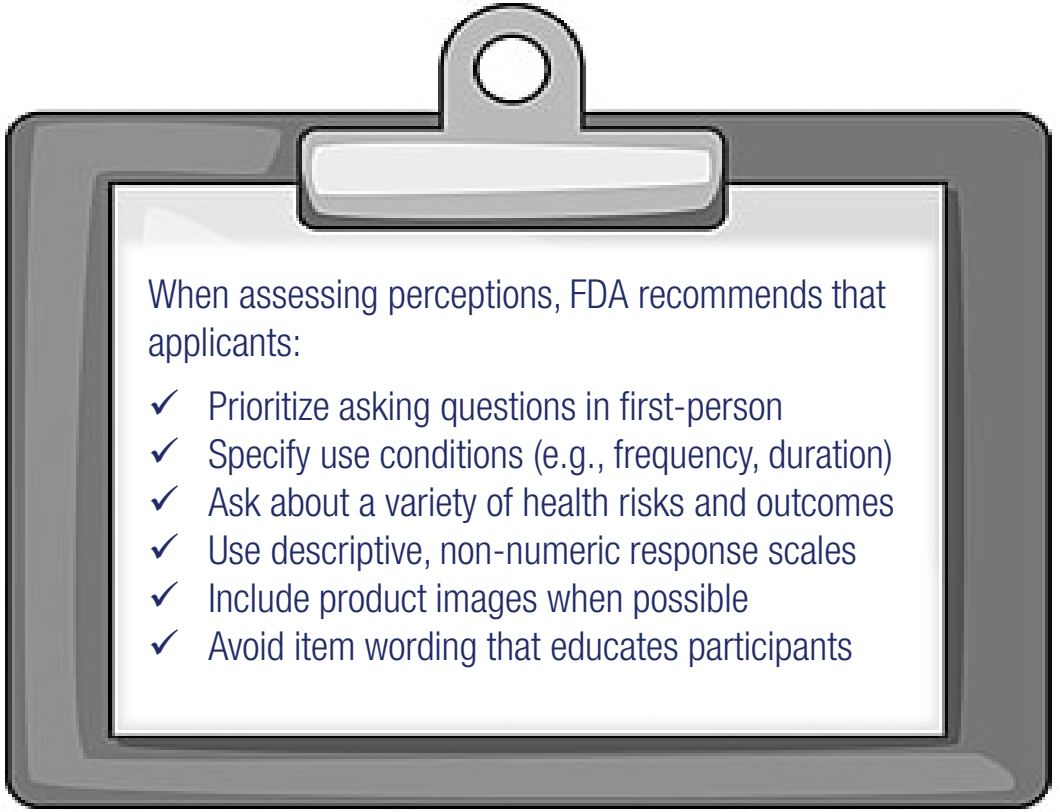
SOME RECOMMENDATIONS IN TPPI STUDY GUIDANCE[1]

FDA Guidance for Industry: Principles for Designing and Conducting Tobacco Product Perception and Intention (TPPI) Studies

Consider using an experimental design in which participants are randomly assigned to view the proposed modified risk LLA (or a control condition) and then answer questions about the LLA and product risks.

If measures will be used to assess understanding, FDA recommends that applicants:

- ✓ Include more than one type of measure
- ✓ Include a measure with items scored for accuracy
- ✓ For scorable items, don't make them too easy



When assessing perceptions, FDA recommends that applicants:

- ✓ Prioritize asking questions in first-person
- ✓ Specify use conditions (e.g., frequency, duration)
- ✓ Ask about a variety of health risks and outcomes
- ✓ Use descriptive, non-numeric response scales
- ✓ Include product images when possible
- ✓ Avoid item wording that educates participants

[1] Guidance with full text of recommendations available at https://www.fda.gov/media/143322/download.

IMPORTANCE OF VALIDITY

- Measures should be valid, meaningful reflections of consumer understanding.
- When evaluating validity, the TPPI Study Guidance describes factors we consider such as:

Face validity
The apparent connection between the measure and construct, and lack of apparent bias in how items and response options are written and presented

Cognitive testing
The applicant cognitively tested the items to determine that participants correctly interpreted what the items are asking

Published validation
Items were previously used in published studies demonstrating their validity (e.g., through statistical relationships with validated measures of related constructs)

Applicant validation
The applicant conducted or sponsored validation studies on the items

ADDITIONAL CONSIDERATIONS

- FDA's evaluation of consumer understanding in MRTPAs is focused on the adequacy of people's understanding after viewing the modified risk LLA.
  - We do not have specific thresholds (e.g., ≥80% correct responses on certain survey items).
  - Our evaluation is holistic, considering everything we know about the product, LLA, and research.
  - We have also considered whether the modified risk LLA could *improve* people's understanding (i.e., beyond being sufficiently understood, could help address entrenched existing beliefs).

QUESTIONS FOR THE COMMITTEE

DISCUSSION QUESTION #1

We presented a potential framework for conceptualizing what aspects of consumer understanding should be demonstrated in MRTPAs. The potential framework had three components:

- Understanding what risk or exposure reduction is described
- Understanding that the proposed MRTP is more harmful than non-use and cessation
- Understanding how to use the proposed MRTP to reduce one's risk or exposure

What does the Committee think of this potential framework? Does the Committee suggest any modifications?

DISCUSSION QUESTION #2

In most studies of consumer understanding of modified risk LLA, participants view the LLA as part of a controlled laboratory experiment, whereas in the real world, consumers could be exposed to LLA repeatedly and in various advertising formats.

A. Does the Committee expect consumer understanding to differ between real-world and experimental settings? If so, how should we account for this in study designs or evaluation of experimental studies?
B. What does understanding in the real world look like and how could CTP and applicants monitor consumer understanding as part of postmarket surveillance following an authorization?

DISCUSSION QUESTION #3

As covered in the presentation, there may be unique consumer understanding considerations for the intended and unintended users of an MRTP.

A. Should consumer understanding be assessed differently for various populations?

B. What are possible red flags that indicate consumers are misled or not understanding and how could those red flags be measured?

DISCUSSION QUESTION #4

Consumers (study participants) bring with them pre-existing beliefs that affect how they interpret claim information and answer survey questions. For example, the majority of the public believes smokeless tobacco products are equally as harmful or more harmful than cigarettes.

How, if at all, should FDA take pre-existing beliefs into account when assessing and evaluating consumer understanding of proposed MRTP claims?