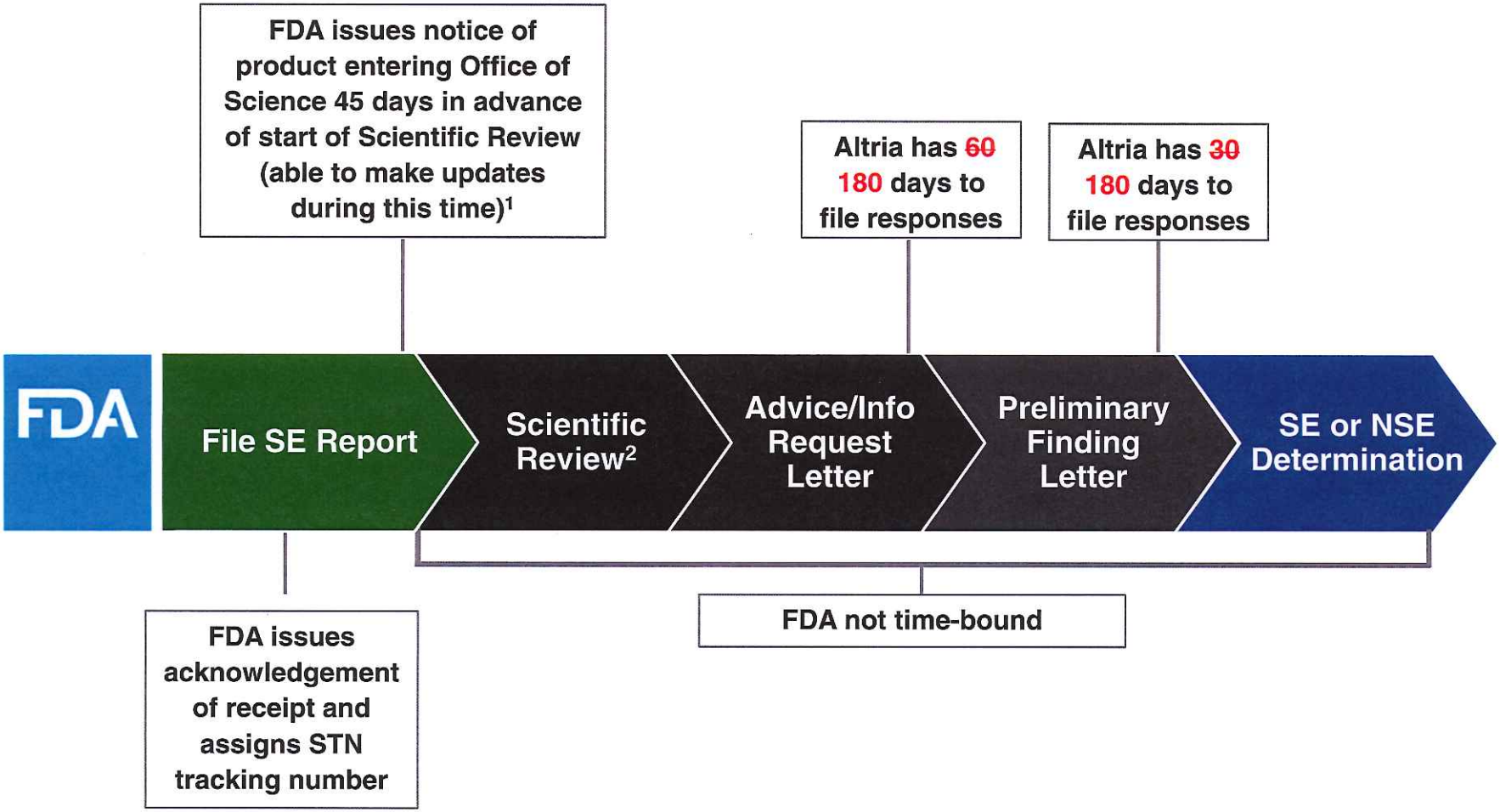
FDA Substantial Equivalence Process



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[1] Applicable to Provisional filings only, not Regular filings
[2] FDA may issue Administrative Advice/Info Request and Preliminary Finding letters once filings enter scientific review

Meeting with the Office of Management and Budget

Joe Murillo
Sr. Vice President, Regulatory Affairs

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November 9, 2018

Altria's Tobacco Operating Companies

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PhilipMorrisUSA
an Altria Company

U.S. Smokeless
TOBACCO CO.
an Altria Company

John Middleton
an Altria Company

NuMark
An Altria Innovation Company

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Rules of the Road

"We all need to be on the same page regarding the basic "rules of the road," especially when it comes to what's expected in premarket applications."

...

"Establishing a rigorous, predictable, science-based framework for the premarket review of tobacco products is a key element of our program."

~ Scott Gottlieb, M.D., and Mitch Zeller, J.D.

Source: Gottlieb, Scott and Zeller, Mitch, "Advancing Tobacco Regulation to Protect Children and Families: Updates and New Initiatives from the FDA on the Anniversary of the Tobacco Control Act and FDA's Comprehensive Plan for Nicotine," Aug. 2, 2018, *at* https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm619118.htm

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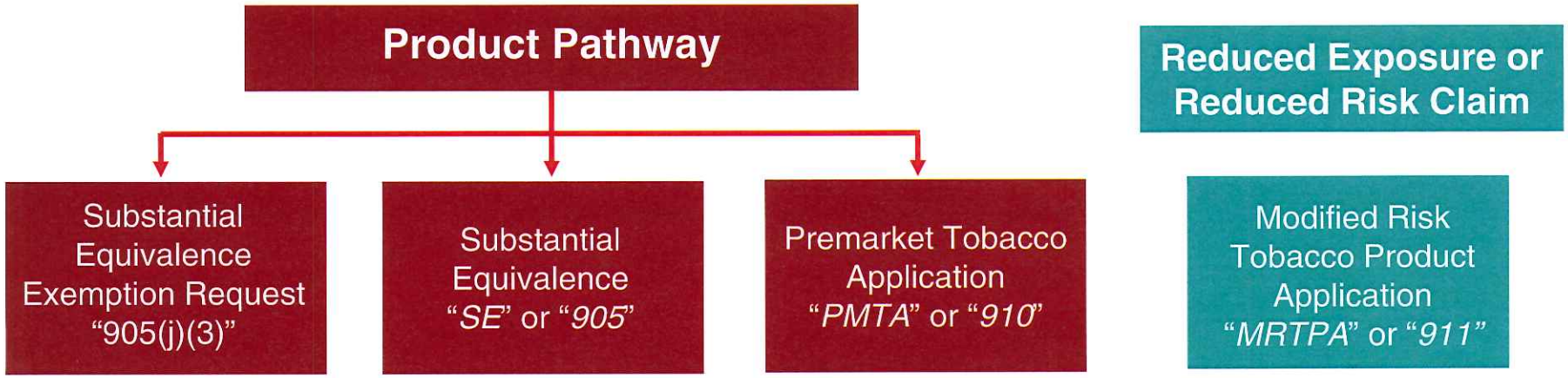
FDA Market Pathways



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Two Prongs of Substantial Equivalence

The TCA requires FDA to issue a marketing order for a new tobacco product if it:

- (i) has the *same characteristics* as a predicate tobacco product;

or

- (ii) has *different characteristics* and the information submitted contains information . . . that demonstrates that… the product does not raise *different questions of public health*."*

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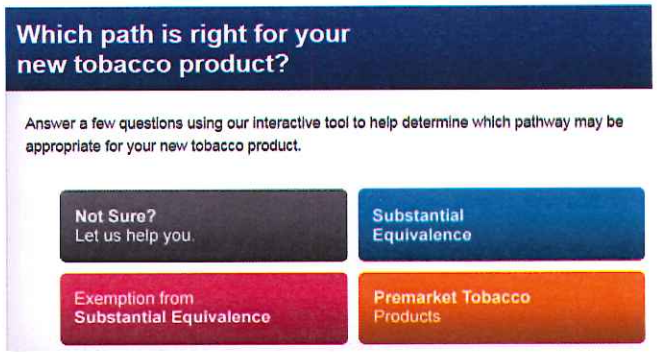
* TCA §§ 910(a)(3)(A)(i)–(ii)(emphasis added).

SE Key Issues

- Still lacking foundational rules
  - Definitions for "same" vs. "different" characteristics
  - Standards for "does not raise different questions of public health"
- Lack of consistency across reviewers and over time
- Limitations on changing predicate
- EA categorical exclusion for all SE submissions

FDA U.S. FOOD & DRUG ADMINISTRATION



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Definitions

- **Same Characteristics** - means that the products being compared have similar, but not identical, materials, ingredients, design, composition, heating source or other features; and the differences are not material to a public health risk assessment of the new product

- **Different Characteristics** - means the products being compared have material differences in materials, ingredients, design, composition, heating source or other features, such that there is potential to raise different questions of public health.

- **Different Question of Public Health** - a risk to public health not already presented by products in the same category that were on the market as of February 15, 2017.

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