Tobacco Product Applications: FDA Perspective

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Disclaimer: This information is not a formal dissemination of information by the FDA and does not represent Agency position or policy.

EX & SE Performance Goals

- EX & SE performance measures established in FY15-18
- Recently announced performance measures for FY19-22
- Statutory products
- Regular *& provisional* SE Reports
- Revised measures to improve clarity
- Revised measures to better align EX & SE goals

EX & SE Performance Goals

Performance Measure	FY17	FY18	FY19	FY20	FY21	FY22
Regular SE Reports						
Issue ACK, RTA, or Withdrawal ACK letter ≤21 days	70%	80%	80%	80%	80%	80%
Issue A/I, PFind, Cancellation, Closure, SE or NSE order letter ≤90 days	70%	80%	80%	80%	80%	80%
Provisional SE Reports						
Issue Withdrawal ACK letter ≤21 days	n/a	n/a	50%	60%	70%	80%
Issue A/I, PFind, Cancellation, Closure, SE or NSE order letter ≤120 days	n/a	n/a	50%	60%	70%	80%
Exemption Requests						
Issue ACK, RTA, or Withdrawal ACK letter ≤21 days	n/a	n/a	80%	80%	80%	80%
Issue A/I, Cancellation, Closure, EX or NEX order letter ≤60 days	70%	80%	80%	80%	80%	80%

Increased Focus: Closing Active Reviews

Pre-June 2017

- Reviewing regular SE Reports & EX REQs as received
- Reviewing provisional SE Reports that had received Notification letters
- Issuing Notification letters each month for provisional SE Reports

Increased Focus: Closing Active Reviews

Post-June 2017

- Reviewing regular SE Reports & EX REQs as received
- Reviewing provisional SE Reports that had received Notification letters
- Not issuing Notification letters each month for provisional SE Reports
- Focus on completing reviews that are active

Increased Focus: Remove From Review

- Reviewing regular SE Reports & EX REQs as received
- Remove From Review (RFR) PHI tiers 3 & 4
  - ~1,500 SE Reports may be RFR
  - ~900 confirmed new tobacco product was commercially marketed between February 15, 2007, & March 22, 2011
  - ~600 require valid first commercial marketing date
- ~1,000 provisional SE Reports remain in review queue
- Allows FDA to focus on provisional SE Reports most likely to impact public health

CTP Process Improvements in Past Year

- Greater clarity on priorities within EX & SE programs
- Better alignment of staff on work related to EX & SE actions
  - More effective collaboration across multidisciplinary review teams
- Identified steps in the review process that could be shortened
  - Remove redundancies by different staff

Differences between EX/SE & PMTA Programs

- Statutory basis for marketing order

- Additional steps in PMTA review process

Similarities between EX/SE & PMTA Programs

- Early stages of PMTA review
  - Few PMTAs have made it past the acceptance & filing stages
- Expect learning curve in PMTA program as experienced with EX & SE programs
  - CTP & applicants are learning
  - Pre-PMTA meetings are helpful
- Will publish PMTA ENDS final guidance soon

FDLI Annual Conference – FDA Implementation of Tobacco Product Pathways

Joe Murillo
Vice President, Regulatory Affairs
May 3, 2018

Altria

FDA Authorization Pathways

A manufacturer must obtain authorization from FDA in connection with marketing a new tobacco product

There are three product pathways by which a manufacturer may obtain FDA authorization

Substantial Equivalence Exemption Request "905(j)(3)"

Substantial Equivalence "*SE*" or "*905*"

Premarket Tobacco Application "*PMTA*" or "*910*"

Need for Foundational Rules

"We didn't have any of the foundational rules in place to even…describe how to submit…and what should be in an application…"

- Commissioner Scott Gottlieb, MD

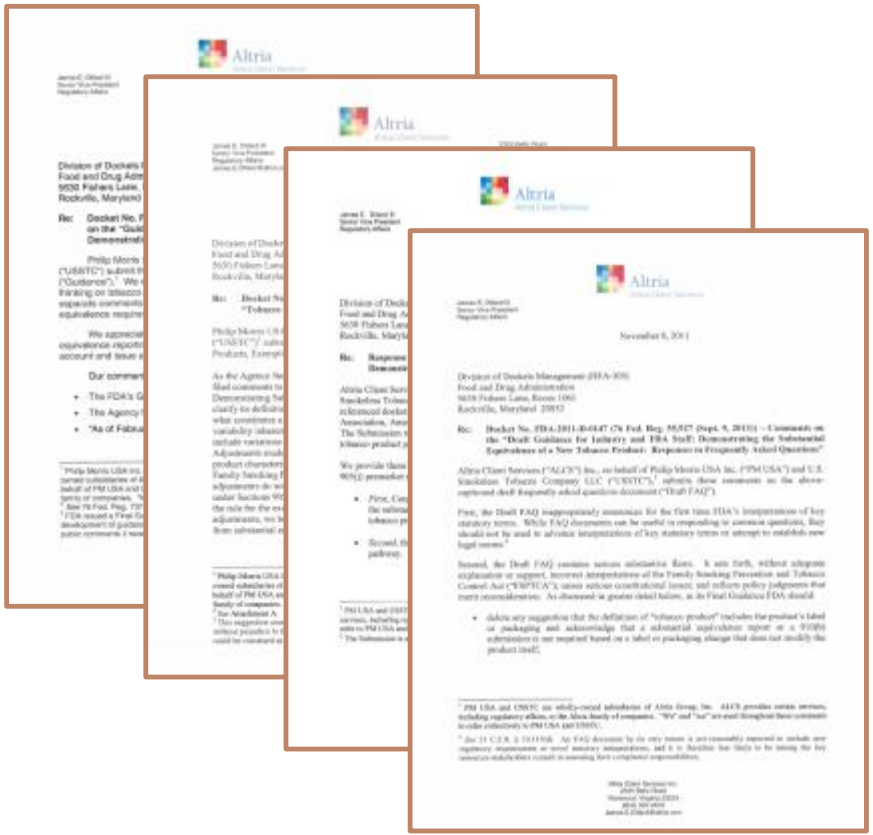
"Our goal is to work through the remaining SE submissions in a consistent, transparent and predictable manner."

- Mitch Zeller, JD, Director, CTP

FDA U.S. FOOD & DRUG ADMINISTRATION

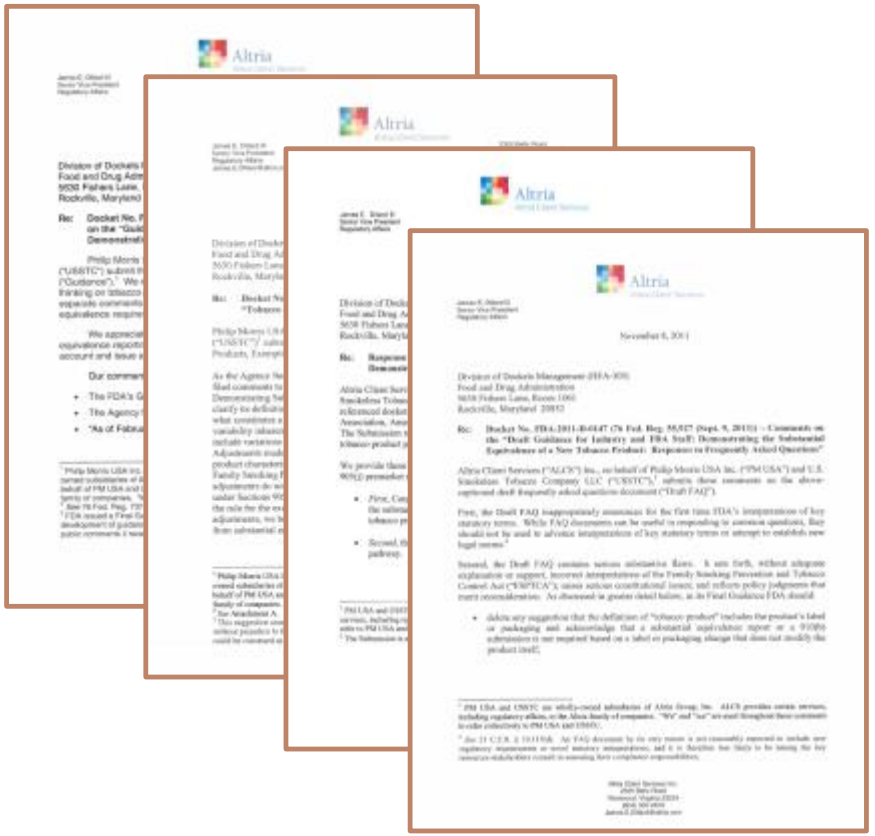
Implement a Clear and Correct Interpretation of the SE Pathway

- Recognize and distinguish between the two “prongs” of the SE pathway
- Define “same characteristics” and “different characteristics” prongs of the SE pathway
- Establish standards for determining when a tobacco product presents “different questions of public health”



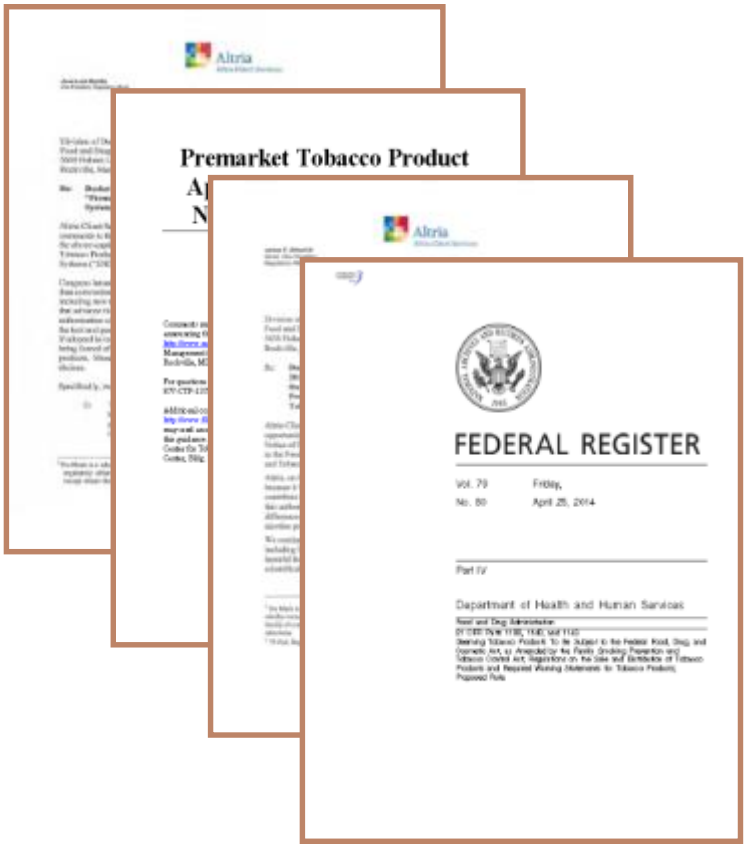
Define the Required Content and Format of SE Applications

- Define the least burdensome content required to demonstrate SE
- Potential for tiered approach
- Recognize that FDA's review solely pertains to a product's characteristics
- Clarify how applicants may use surrogate product information
- Establish clear and consistent review procedures
- Set reasonable and predictable review timeframes



PMTA Pathway Should be Modified

- ENDS PMTA process is unduly burdensome
  - Complexity may force products off the market
  - Certain data requests unrelated to assessing public health impact
- Need an accelerated review process and a change management process after issuance of a market order
- Interaction with potential product standards



Questions

Greenleaf Health

Substantial Equivalence:
A Medical Device Perspective

Dan Schultz, MD, FACS,

Principal, Medical Devices and Combination Products, Greenleaf Health Inc.

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WHAT DOES "SUBSTANTIAL EQUIVALENCE" MEAN?

The term "substantially equivalent" is not intended to be so narrow as to refer only to devices that are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purposes as marketed products. The Committee believes that the term should be construed narrowly where necessary to assure the safety and effectiveness of a device but not so narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness.

House Report No. 853, 94th Congress, 2d Session 36-37 (1976)

WHAT DOES "SUBSTANTIAL EQUIVALENCE" MEAN?

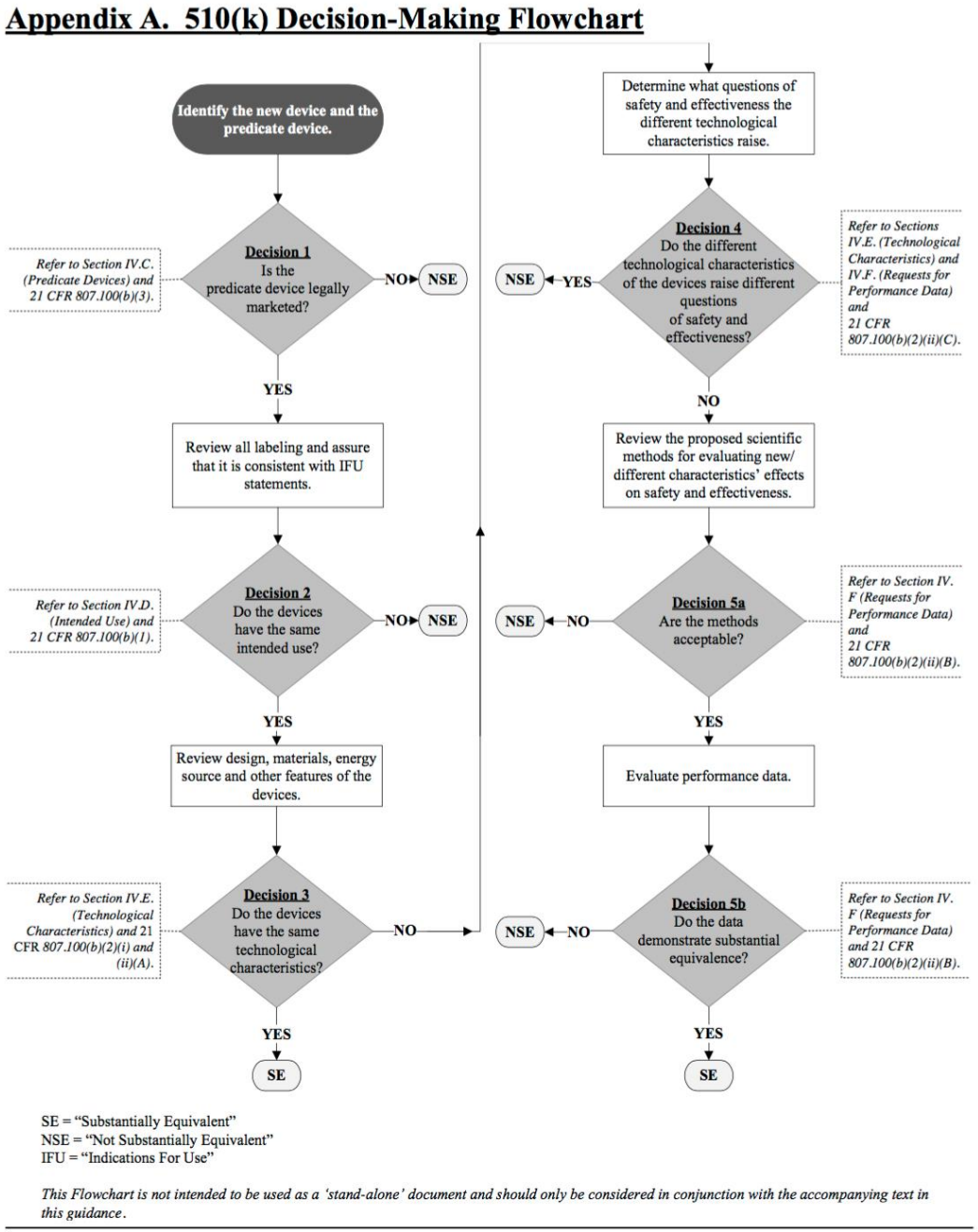
- "Substantial equivalence" to a lawfully marketed predicate device is the review standard for 510(k) devices.
- A "substantially equivalent" device:

  (1) must have the same intended use as the predicate device, and

  (2) (i) must have the same technological characteristics as the predicate device, or

  (ii) if it has different technological characteristics, must be supported by information and data demonstrating that the device is as safe and effective as a legally marketed device and does not present different questions of safety or effectiveness.
- "Different technological characteristics" means "a change in the materials, design, energy source, or other features of the device from those of the predicate device."

The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)] – [Guidance for Industry]



EXAMPLES – INTENDED USE

- Same intended use -- both 510(k)
  - Scalpel for cutting soft tissue
  - Laser for cutting soft tissue

- Different intended uses
  - IVD for monitoring PSA levels -- (510(k))
  - IVD for diagnosing prostate cancer -- (PMA)

The “regulatory term” to distinguish 510(k) from PMA

EXAMPLES – TECHNOLOGICAL CHARACTERISTICS

- Predicate surgical instrument cuts tissue using radiofrequency power, and new instrument cuts with a laser
- Predicate vascular catheter is uncoated, and new catheter has a lubricious coating
- Predicate infusion pump flow is adjusted by a knob, and new pump via software

STUDIES OF THE 510(K) PROGRAM

- 1984-1985 FDA 510(k) Criticism Task Force
- 1988 GAO 510(k) Study
- 1989-1990 HHS Inspector General 510(k) Study
- 1997 FDA 510(k) Reengineering
- 2008-2009 GAO 510(k) Study
- 2009-2010 FDA 510(k) Study
- 2010-2011 IOM 510(k) Study

QUESTIONS?

Thank you