SUBSTANTIAL EQUIVALENCE
2019 UPDATE

Presented by
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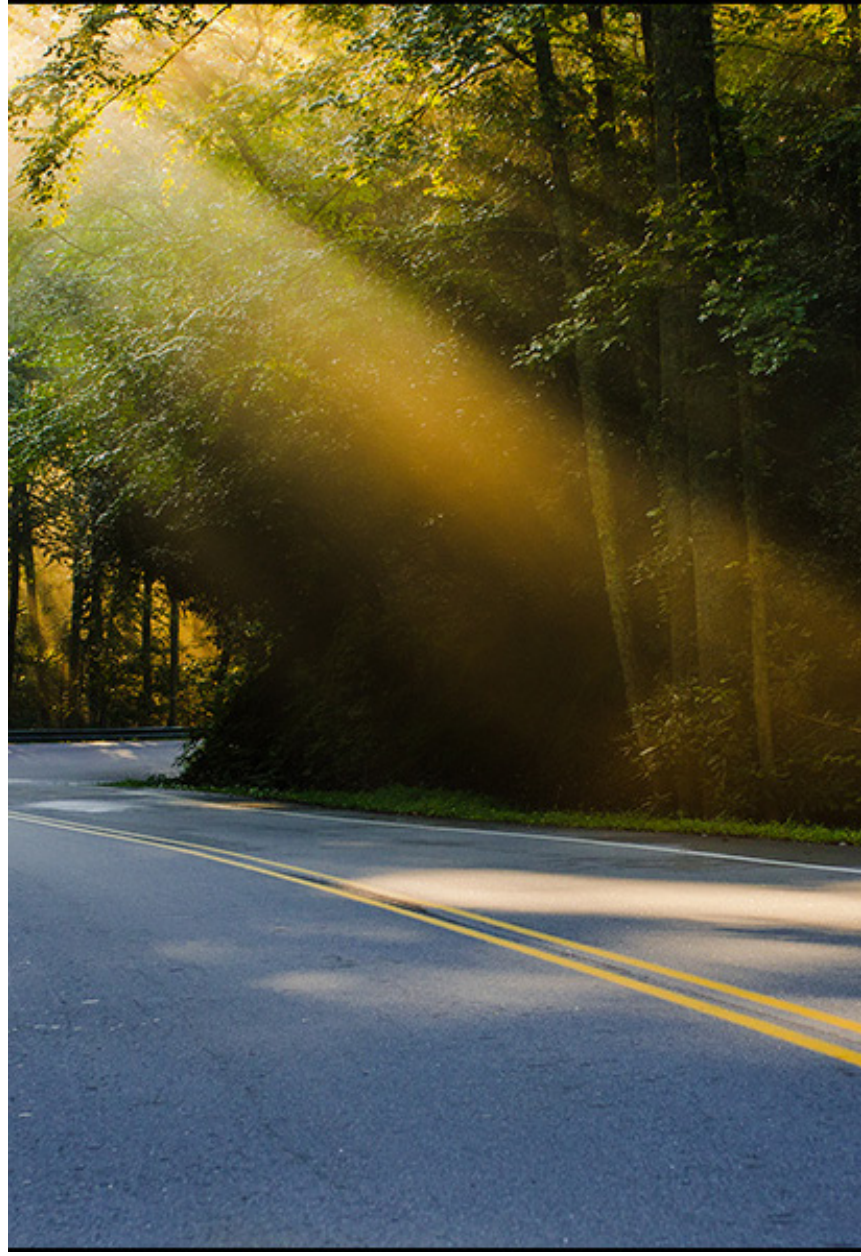
RHPM, Division of Regulatory Health Project Management
Office of Science
Center for Tobacco Products
U.S Food and Drug Administration



- **Part I: SE Program Overview**
  - Statutory Authority
  - Standard
  - Regulars vs Provisionals
  - Review Process Phases
- **Part II: SE Program Updates**
  - Letter Updates
  - SE Policy Memos
  - SE Rule Update
- **Part III: SE Metrics**

PROGRAM OVERVIEW

STATUTORY AUTHORITY

- The Family Smoking Prevention and Tobacco Control Act authorizes FDA to establish a premarket program to manage submissions related to substantial equivalence. Specifically, section 905(j)(1) states:

  - In general.-- Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the United States as of February15, 2007, shall, at least 90 days prior to making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall prescribe)--

SUBSTANTIAL EQUIVALENCE STANDARD

- For a determination of substantial equivalence, the manufacturer must demonstrate:
  - that the new product has the same characteristics as the predicate tobacco product;
  - or has different characteristics than the predicate tobacco product but the information submitted demonstrates that the new product does not raise different questions of public health

- This means that products brought to market through this pathway potentially will not present more harm to public health than an eligible predicate tobacco product

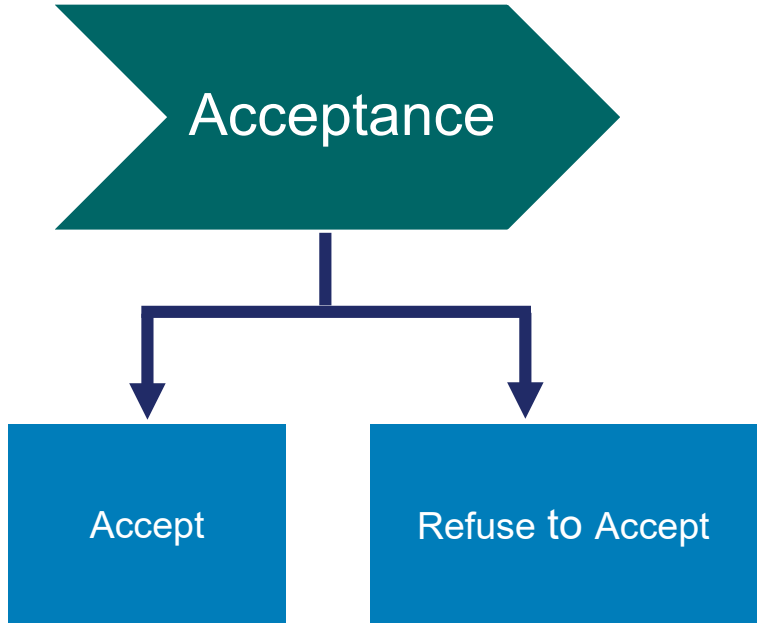
REGULAR AND PROVISIONAL

- Provisional SE Reports are applications for new tobacco products that meet the following statutory criteria:
  - SE Reports were submitted by March 22, 2011, and
  - The products were introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to March 22, 2011
- Regular SE Reports are applications for new tobacco products that require a marketing authorization prior to being introduced to the U.S market

SE REVIEW PROCESS

Phase I: Acceptance

- Step 1: *Application Received* – FDA receives and processes the application.
- Step 2: *Acceptance Review* – FDA reviews the tobacco SE Report to determine if it is under jurisdiction and contains required items.



ACCEPTANCE CRITERIA:

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 authorized to represent an applicant
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

https://www.federalregister.gov/documents/2016/08/08/2016-18534/refuse-to-accept-procedures-for-premarket-tobacco-product-submissions

SE ACCEPTANCE CRITERIA

- FDA may RTA a SE Report application if the following criteria are not met:

Requirement	Authority	APPLICATION CONTENT
1) Basis for SE	905(j)(1)(A) of the FD&C Act	Statement stating applicants basis for SE • Same characteristics • Different characteristics
2) Health Summary/ Statement	910(a)(4)(A) of the FD&C Act	Summary or scientific literature addressing the health affects of the tobacco product **Or** Statement that "Information will be made available upon request by any person"
3) Compliance with 907	907(a)(1)(A) & 907(a)(1)(B) of the FD&C Act	Statement stating compliance with 907 • Characterizing flavor • Pesticide chemical
4) Environmental Assessment or Valid Cat Ex	21 CFR 1105.10	Environmental assessment or claim of categorical exclusion

Acceptance

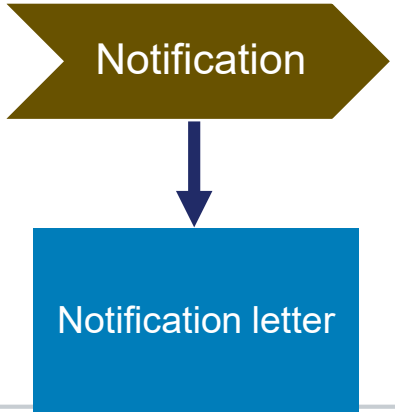
Phase II: Notification

- Step 4: *Predicate Determination* – FDA conducts a review to ensure the predicate tobacco product is eligible

❑ A tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007

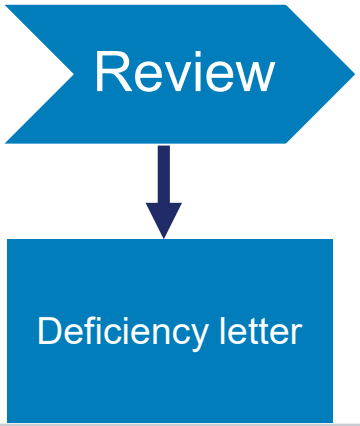
OR

❑ A product previously found to be substantially equivalent by the FDA and in compliance with the requirements of the FD&C Act



Phase III: Review

- Step 5: *Review* – Generally SE Reports are assigned a chemistry, toxicology, engineering and environmental reviewer. Additional scientific evaluation can include social science, addiction, and clinical.
- Step 6: If necessary, a deficiency letter will be issued.
- Step 7: *Final SE Determination* – FDA determines whether the new tobacco product is substantially equivalent (SE) or not-substantially equivalent (NSE) to a predicate product.

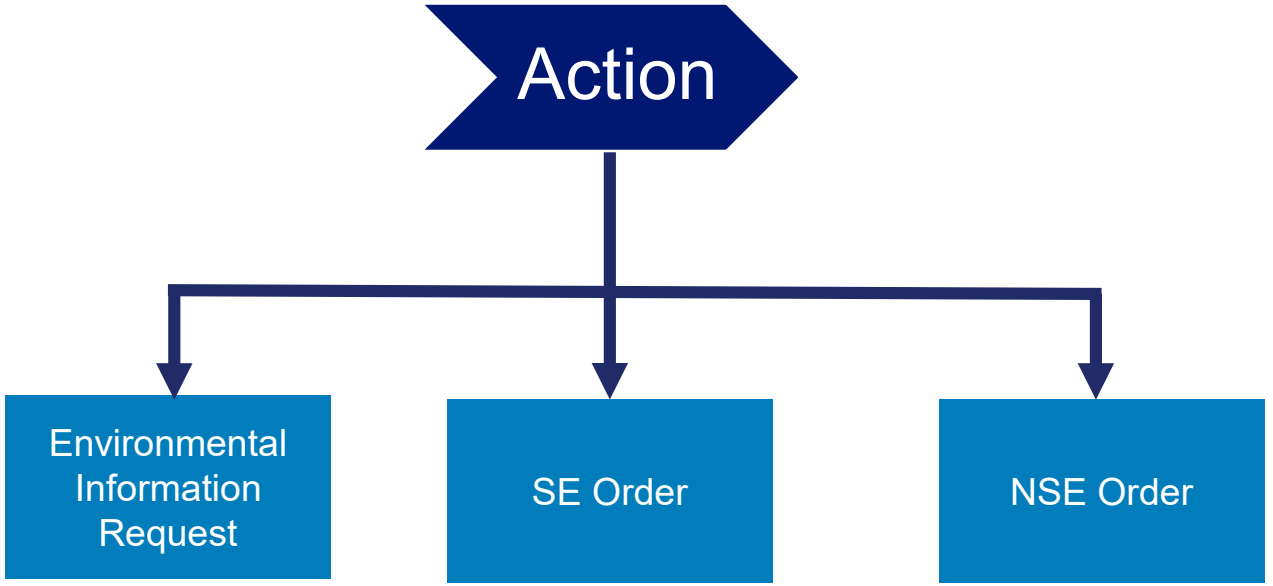


Phase III: Action

- Step 8: Environmental Consideration – If the SE Report has been found SE from a scientific perspective and additional information is needed, the applicant receives a letter requesting the additional information.
- Step 9: Compliance Review – For Regular SE Reports FDA must determine that the new tobacco product is in compliance with the requirements of the FD&C Act.

Phase III: Action

- Step 10: Courtesy Call – Once the final TPL and order letter is signed the RHPM will contact the applicant and offer a courtesy copy via email.
- Step 11: Website Posting – The final TPL review and order letter are posted to the FDA website.



TIMELINE

- Acceptance letter
- Notification letter
- Deficiency letter
- Environmental Information Request letter
- SE Order Letter
- NSE Order Letter

PROGRAM UPDATES

LETTER UPDATES

- **The goals for these updates are:**
  - Reduce confusion by using plain language
  - Increase clarity by ensuring the purpose of letter and next steps are upfront
  - Simplify and standardize language across all programs
  - Simplify and standardize letter format across all programs
  - Remove supplemental information and place in appendices

LETTER TYPES

Formally know as		Current terminology
Acknowledgement		Acceptance
Advice Information Request & Preliminary Finding*		Deficiency
Advice Information Request (for environmental considerations)		Environmental Information Request

* The name change for these letters was effective September 2018

U.S. FOOD & DRUG ADMINISTRATION

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

FDA 10 YEARS TOBACCO CONTROL ACT

DEFICIENCY

Company Name
Attention: Authorized Contact, Title
Address
Address

FDA Submission Tracking Numbers (STNs): Multiple STNs, see Appendix A

Dear Authorized Contact:

We reviewed your October 28, 2019, SE Reports[1] and concluded that additional information is needed for a determination of substantial equivalence for the tobacco products identified in Appendix A. Refer to Appendix B for a list of amendments received in support of your applications.

We request that you submit all the information identified below within 180 calendar days from the date of this letter. We have determined this timeframe will be sufficient to respond and do not intend to provide an extension of time.

We have preliminarily determined that these applications do not in their present form support a positive scientific determination. We will evaluate the information in your timely response to this letter prior to issuing an appropriate order. We expect that no more Deficiency letters will be issued for these applications.

The following information is necessary for FDA to make a scientific determination:

Refer to Appendix C for health information summary.

When responding to this letter, you should send an amendment with a cover letter that includes the following text in your subject line: "**RESPONSE TO DEFICIENCY LETTER for SEXXXXXXX-SEXXXXXXX**." Refer to Appendix D for best practices in submitting a response to a deficiency letter.

We intend to initiate scientific review 181 days from the date of this letter unless you state that you have responded to each numerated deficiency and would like us to begin prior to day 181. To notify us, clearly state (by STN) that you have responded to each numerated deficiency above and request that scientific review start with receipt of your response. Please be advised that an inadequate resolution of the deficiencies described above, or a late response, will likely result in not substantially equivalent determinations. We are not obligated to review subsequent amendments that are received after the start of scientific review.

If you have any questions, please contact Lauren DeBerry, M.P.H., Regulatory Health Project Manager, at (888) 888-8888 or Lauren.Deberry@fda.hhs.gov.

Sincerely,

Jeannie Jeong-Im, Ph.D.
Chemistry Branch Chief
Division of Product Science
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A – New Tobacco Products Subject of This Letter
Appendix B – List of Amendments Received for These Applications
Appendix C – Health Information Summary
Appendix D – Best Practices for Submitting a Response to a Deficiency Letter

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Chemistry Branch Chief
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POLICY MEMOS

- On July 2, 2019, FDA released scientific review policy memoranda that provide details on key areas of regulatory science that are part of the tobacco product application review process.
- These memos, developed between 2014 and 2019, were written to assist FDA's reviewers with the evaluation of new tobacco product applications in discipline areas such as chemistry, toxicology, engineering, social science, behavioral and clinical pharmacology, and microbiology.
- The information contained in these memos is subject to change based on advances in policy and regulatory science and is not binding on FDA or the public. The memos may serve as a useful additional reference; however, they should not be viewed as a comprehensive manual for preparation or review of tobacco product applications.

SE RULE UPDATE

- FDA issued a proposed rule “Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports” that when final will establish requirements for the content and format of reports manufacturers must send to the agency to demonstrate the substantial equivalence (SE) of a new tobacco product. This proposed rule will also provide information as to how the agency intends to evaluate these reports.

- FDA solicited public comments April 2, 2019, through June 17, 2019.

SE METRICS

SE APPLICATIONS BY PRODUCT CATEGORY: STATUTORILY REGULATED PRODUCTS

	Received FY 19	Open FY 19	Closed* FY 19			
			SE	NSE	RTA	Withdrawn
Cigarettes	126	36	83	0	7	0
Roll Your Own	28	13	15	0	0	0
Smokeless	75	13	40	0	0	22
Total	229	62	167			

* Closed means CTP has taken an action on an application. Closed includes refuse-to-accept, refuse-to-file, withdrawn, closure due to administrative issues, environmental information request letter, predicate advice letter, removed from review, or issuance of order letter as applicable to each program

SE APPLICATIONS BY PRODUCT CATEGORY: STATUTORILY REGULATED PRODUCTS CUMULATIVE TOTAL

	Received	Open	Closed*			
			SE	NSE	RTA	Withdrawn
Cigarettes	3684	520	374	275	25	1280
Roll Your Own	1644	31	647	50	16	451
Smokeless	996	131	172	67	6	329
Total	6324	682	5642			

* Closed means CTP has taken an action on an application. Closed includes refuse-to-accept, refuse-to-file, withdrawn, closure due to administrative issues, environmental information request letter, predicate advice letter, removed from review, or issuance of order letter as applicable to each program

SE APPLICATIONS BY PRODUCT CATEGORY: DEEMED PRODUCTS

	Received FY 19	Open FY 19	Closed* FY 19			
			SE	NSE	RTA	Withdrawn
Cigars	44	22	11	0	2	9
Pipe	28	28	0	0	0	0
Water Pipe	1	1	0	0	0	0
ENDS	0	0	0	0	0	0
Other	0	0	0	0	0	0
Total	73	51	22			

* Closed means CTP has taken an action on an application. Closed includes refuse-to-accept, refuse-to-file, withdrawn, closure due to administrative issues, environmental information request letter, predicate advice letter, removed from review, or issuance of order letter as applicable to each program

SE APPLICATIONS BY PRODUCT CATEGORY: DEEMED PRODUCTS CUMULATIVE TOTAL

	Received	Open	Closed*			
			SE	NSE	RTA	Withdrawn
Cigars	71	22	13	0	5	31
Pipe	28	28	0	0	0	0
Water Pipe	245	1	0	0	244	0
ENDS	20	0	0	0	16	4
Other	0	0	0	0	0	0
Total	364	51	313			

* Closed means CTP has taken an action on an application. Closed includes refuse-to-accept, refuse-to-file, withdrawn, closure due to administrative issues, environmental information request letter, predicate advice letter, removed from review, or issuance of order letter as applicable to each program

RESOURCES

- Substantial Equivalence
  - https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/substantial-equivalence
- RFR List and announcements
  - https://www.fda.gov/tobacco-products/ctp-newsroom/fda-update-provisional-substantial-equivalence-se-review-process
- Decision Summaries for SE Program
  - https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-marketing-orders#2
- Performance Measures website
  - https://www.fda.gov/tobacco-products/substantial-equivalence/performance-measures
- General Inquiries
  - AskCTP@fda.hhs.gov

THE END

THANK YOU