ENVIRONMENTAL ASSESSMENTS & CLAIMS OF CATEGORICAL EXCLUSION

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

AGENDA

- National Environmental Policy Act and its purpose
- The environmental assessment (EA) outline for a product application
- Availability of the EA
- The categorical exclusion (CatEx) outline for a product application
- Applicant resources
- An example EA

NATIONAL ENVIRONMENTAL POLICY ACT AND ITS PURPOSE

National Environmental Policy Act of 1969, Sec. 2

- A national policy which will encourage productive and enjoyable harmony between man and his environment

The Purpose of NEPA

- To promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man
- To enrich the understanding of the ecological systems and natural resources important to the nation
- To establish a Council on Environmental Quality

WHY IS AN EA NEEDED?

An EA is required by NEPA for:

- Promulgation of new regulations
- Requests for action, such a product marketing order

Per FDA Regulations:

21 CFR 25.15(a) states “All applications or petitions requesting agency action require the submission of an EA or a claim of categorical exclusion”

USEFUL IN AN OUTLINE OF AN EA FOR A PRODUCT AUTHORIZATION REQUEST

Cover page

Table of Contents

Sections in the EA

Appendices

USEFUL INFORMATION IN THE COVER PAGE OF THE EA

Includes the following information:

- The title of the document, for example “Environmental Assessment for the Marketing Order for [new product name] Manufactured by [name of applicant]”

- The Agency for which the EA was prepared, for example “Prepared for the Center for Tobacco Products, U.S. Food and Drug Administration”

- Date the EA was prepared

USEFUL INFORMATION IN THE TABLE OF CONTENTS

The EA contains a Table of Contents, that includes:

- EA section titles
- EA subsection titles
- Appendices
  - Can be both public and confidential appendices

Each line of the table of contents also includes the associated page numbers

USEFUL INFORMATION IN SECTION 1 – APPLICANT AND MANUFACTURING INFORMATION

Company (applicant) name

- Applicant Address
  - Identifies the business address of the applicant:
    - Street address
    - City, state (province when outside the United States), zip code
    - Country (when outside the United States)

Manufacturer name

- Manufacturer address
  - Identifies the business address of the applicant:
    - Street address
    - City, state (province when outside the United States), zip code
    - Country (when outside the United States)

USEFUL INFORMATION IN SECTION 2 – PRODUCT INFORMATION

New product name

The new product submission tracking number (STN), if available

Predicate product name

Product type and sub-category

Product package design

Product quantity per retail sale unit

SECTION 3 – THE NEED FOR THE PROPOSED ACTION

Useful information:

Identify the requested product application pathway and describe the marketing intent.

For example:

"The proposed action, requested by the applicant, is for FDA to issue a marketing order under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act after finding the new tobacco product substantially equivalent to the predicate product. The applicant wishes to introduce the new tobacco product into interstate commerce for commercial distribution in the United States."

SECTION 3 – THE NEED FOR THE PROPOSED ACTION (CONTINUED)

Useful information:

Identify the predicate product (for SE or request for exemption from SE)

- Status (grandfathered or previously found SE, and dates)

Brief non-confidential description of the new product modifications compared to the corresponding predicate product

- Detailed descriptions are included in a confidential appendix

SECTION 4 – ALTERNATIVES TO THE PROPOSED ACTION

Address relevant alternatives to the proposed action of issuing a marketing order.

For example:

- No-action alternative: “The no-action alternative is FDA does not issue a marketing order for the new tobacco product in the United States.”

SECTIONS 5 – 7 – POTENTIAL ENVIRONMENTAL IMPACT OF THE PROPOSED ACTION AND THE ALTERNATIVES

Useful Information in Section 5: The potential impact from manufacturing of the new product and the alternative action(s)

Section 6: The potential impact from use of the new product and the alternative action(s)

Section 7: The potential impact from disposal of the new product and the alternative action(s)

SECTIONS 5 – 7 – POTENTIAL ENVIRONMENTAL IMPACT OF THE PROPOSED ACTION AND THE ALTERNATIVES (CONTINUED)

Useful Information in Affected Environment

- A descriptive narrative regarding the land use around the manufacturing facility with an aerial photograph.
- Identify the environment where the product will be used.
- Identify the environment where the product will be disposed.

SECTIONS 5 – 7 – POTENTIAL ENVIRONMENTAL IMPACT OF THE PROPOSED ACTION AND THE ALTERNATIVE ACTION(S)

Useful information for each section, if applicable:

- Air quality
- Water resources
- Land use and zoning
- Biological resources
- Geological features and soils
- Socioeconomics and environmental justice
- Solid Waste and hazardous Waste
- Floodplains, wetlands and coastal zones
- Regulatory compliance
- Cumulative Impacts of above
- Mitigation of the impacts when necessary

USEFUL INFORMATION IN SECTION 8 - LIST OF PREPARERS

Lists the individuals primarily responsible for preparing and reviewing the EA. For each individual, provided the following:

- Name
- Title
- Organization
- Relevant education
- Relevant experience
- Relevant expertise

SECTION 9 – A LISTING OF AGENCIES AND PERSONS CONSULTED

Useful information for the list of any agencies or persons consulted during the preparation of the EA:

- Name
- Title
- Organization

USEFUL INFORMATION IN SECTION 10 – REFERENCES

The reference section provides a list of the references that were used in preparing the EA.

USEFUL INFORMATION IN APPENDICES

An EA can include two types of appendices, ones that contain non-confidential information and ones that contain confidential information. Both contain information that would support the EA

<u>Confidential Appendices</u>

- Examples of information deemed confidential
  - Modifications or changes between the new and predicate products
  - Calculations made based on confidential information about the new and predicate products or original products, often related to the projected market share information
  - The identities of the suppliers when they are not part of the company that submits the application
  - Suppliers' manufacturing facility location

THE EA IS AVAILABLE TO THE PUBLIC

21 CFR 25.51 (a) Data and information that are protected from disclosure by 18 U.S.C. 1905 or 21 U.S.C. 331(j) or 360j(c) shall not be included in the portion of environmental documents that is made public. When such data and information are pertinent to the environmental review of a proposed action, an applicant or petitioner shall submit such data and information separately in a confidential section and shall summarize the confidential data and information in the EA to the extent possible.

21 CFR 25.51 (b) FONSIs and EAs will be available to the public in accordance with 40 CFR 1506.6

THE CATEGORICAL EXCLUSION OUTLINE FOR A PRODUCT AUTHORIZATION REQUEST

21 CFR 25.15(1) … A claim of categorical exclusion shall include a statement of compliance with the categorical exclusion criteria and shall state that to the applicant's knowledge, no extraordinary circumstances exist.

The only CatEx that is relevant to tobacco product applications is for provisional products submitted through the SE pathway.

- 21 CFR 25.35(a) Issuance of an order finding a tobacco product substantially equivalent under section 910(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

APPLICANT RESOURCES

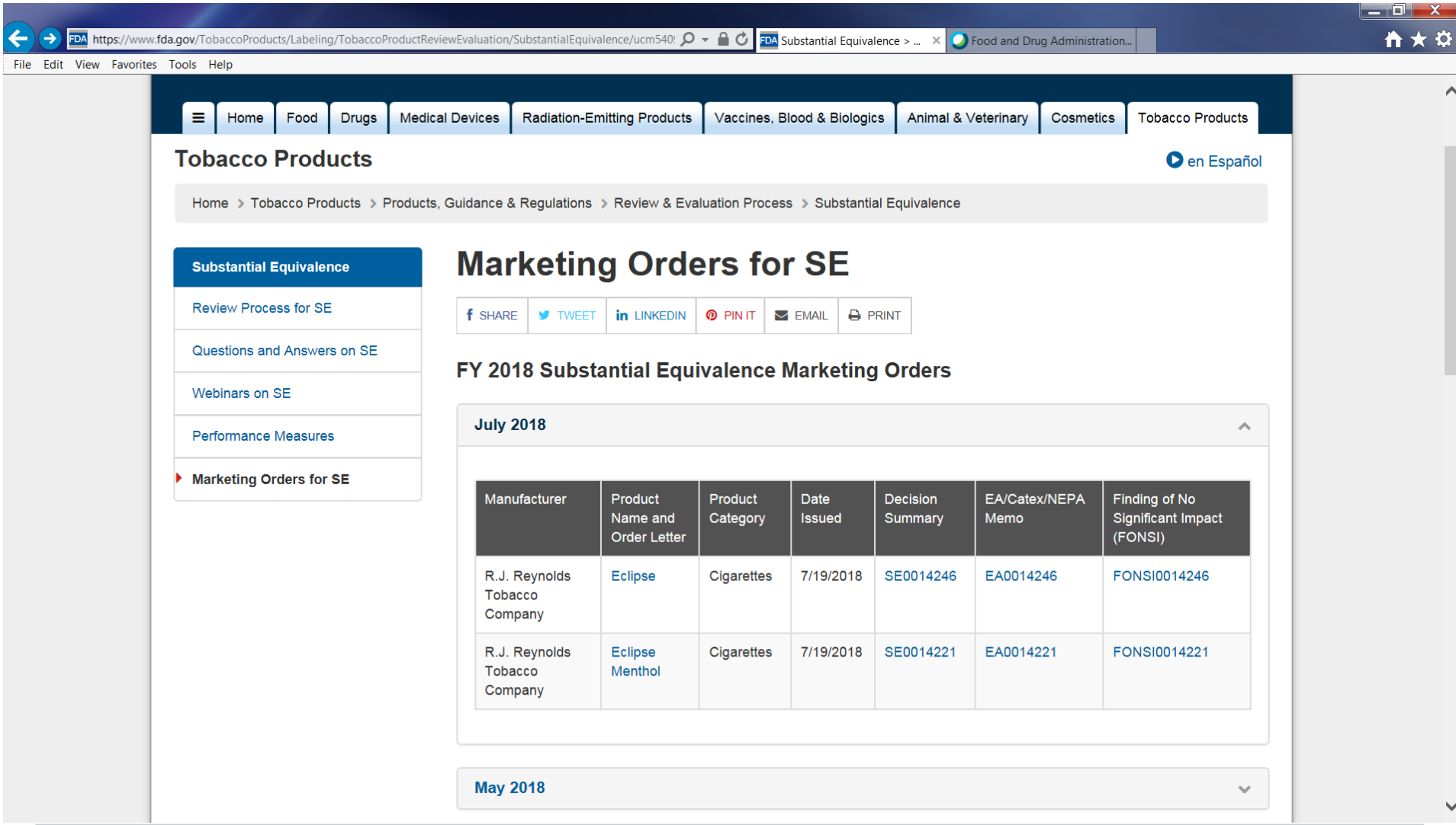
Examples of EAs posted on the CTP website:

- https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/SubstantialEquivalence/ucm540964.htm

CTP Tobacco Compliance Webinar web page

- "Environmental Considerations for Tobacco Product Applications Submitted to CTP", 2016 http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm220111.htm

EXAMPLE EAs CAN BE FOUND ON FDA's WEB PAGE



EXAMPLE EA

Cover page

Programmatic Environmental Assessment for Marketing Orders for Two New Non-Combusted, Filtered Cigarettes by R.J. Reynolds Tobacco Company

Prepared by Center for Tobacco Products, U.S. Food and Drug Administration

July 17, 2018

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EXAMPLE EA (CONTINUED)

Product name

1. [illegible]nt and Manufacturer Information

Applicant Na[illegible]	RAI Services Company on behalf of R.J. Reynolds Tobacco Company
Applicant Add[illegible]	401 N Main St. Winston Salem, NC 27101
Manufacturer Name:	R.J. Reynolds Tobacco Company
Product Manufacturing Address:	Shorefair, a manufacturing facility within R.J. Reynolds Tobacco Company's Whitaker Park Complex, 2901 Shorefair Drive, Winston-Salem, NC 27105

2. Product Information

New Product Names, Submission Tracking Number (STN), and Predicate Product Name

New Product Name	STN	Predicate Product Name
Eclipse	SE0014246	Eclipse Menthol
Eclipse Menthol	SE0014221	Eclipse Menthol

Product Identification

Product Type	Cigarette
Product Subtype	Non-Combusted Filtered
Product Package	Twenty cigarettes per pack with ten packs per bleached sulphate board carton. The pack consists of a solid bleached sulphate board box, foil inner liner, C2S 100# paper pack insert, bleached sulphate board Inner frame, and an oriented polypropylene film overwrap.

Need for the proposed action

The proposed actions, requested by the applicant, are for FDA to issue marketing orders finding the new tobacco products substantially equivalent to the single predicate product under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States. The Agency shall issue marketing orders if, after considering the substantial equivalence (SE) reports submitted by the applicant, the new products are found substantially equivalent to the predicate product. The predicate product was on the market as of February 15, 2007.

In the SE Reports, the new and predicate products are heat-not-burned tobacco products. SE0014246 differs from the predicate product in tobacco mass, tobacco blend, additives, structural materials, and aspects of the heating source; the predicate product contains the characterizing flavor of menthol while the new product does not (Confidential Appendix 1). SE0014221 differs from the predicate product in tobacco mass, tobacco blend, additives, structural materials, aspects of the heating source, and levels of menthol (Confidential Appendix 1).

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Impacts of manufacturing the new product

4. Alternative to the Proposed Actions

[illegible]e no-action alternative is FDA does not issue the marketing orders for the new tobacco products.

5. Potential Environmental Impacts of the Proposed Actions and Alternative –Manufacturing the New Products

The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts based on Agency-gathered information and the following information submitted by the applicant:

- There will be no changes between how the new and predicate products are manufactured.
- The new products are intended to compete with combusted cigarette products currently marketed.
- No facility expansion or new construction is due to the manufacturing of the new products.
- Manufacturing the new products will not require additional resources (e.g., landfills, recycling centers) for disposal of manufacturing waste.

5.1 Affected Environment

The new products are manufactured at the address listed in section 1 of this document (Figure 1).

Figure 1. Location of the Manufacturer

The facility is located in the Yadkin River Headwaters, which occupies the north-western portion of North Carolina in Forsyth County and land use varies from generally undisturbed in the western highlands to decidedly urban in the eastern portion of the watershed around the Winston-Salem metro

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EXAMPLE EA (CONTINUED)

Impacts of use the new product

Impacts of disposal of the new product

List of preparers

nd use within the watershed is predominantly forest (57%). Agriculture and developed areas ac… approximately 24% and 13% of the watershed, respectively.[1]

The aff… nvironment includes human and natural environments surrounding the facility.

5.2 Air Quality

The Agency does not anticipate any new substances or new type of emissions to be released into the environment because of manufacturing the new products. The applicant stated that the facility does not anticipate a change to the facilities' air permit from the manufacture of the new products. In turn, the same or similar substances and types of emissions associated with tobacco products currently manufactured at the facility would be released into the environment as a result of manufacturing the new products.

5.3 Water Resources

The Agency does not anticipate that manufacturing the new products would cause any new chemicals to be discharged into the water. The applicant stated that the facility does not anticipate a change to the facilities' storm water permit from the manufacture of the new products. In turn, the same or similar substances and types of water discharge associated with tobacco products currently manufactured at the facility would be released into the environment as a result of manufacturing the new products.

5.4 Soil, Land Use, and Zoning

The Agency does not anticipate that manufacturing the new products would lead to changes in soil land use, or zoning. The applicant stated that facility expansion or new construction due to manufacturing

5.5 Biological Resources

The … cy does not anticipate that manufacturing the new products would jeopardize the continued exist… any listed species or result in the destruction or adverse modification of the habitat of any such sp… ntified under the Endangered Species Act (ESA). The applicant consulted the U.S. Fish and Wildli… s' (U.S. FSW) critical habitat and endangered species maps. The applicant stated that none of the p… als to be used in the new products are manufactured using any of the endangered or threatened species listed by the U.S. Fish and Wildlife Service.[2,3]

[1] https://files.nc.gov/ncdeq/Water%20Quality/Planning/BPU/BPU/Yadkin/Yadkin%20Plans/2010%20Plan/2_03040101%20Yadkin%20River%20Headwaters-2010.pdf. Accessed June 8, 2018.

[2] U.S. Fish and Wildlife Services (U.S. FWS), available at: https://www.fws.gov/endangered/.

[3] Critical habitat map available at: https://databasin.org/datasets/d579d87eb54f4374a77ea53e7ef66449

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7.4. Water Resources

No changes in impacts on water resources are expected due to disposal of the used cigarette from the new products because the chemicals in the new products are similar to those in currently marketed combusted, filtered cigarettes.

7.5. Socioeconomics and Environmental Justice

The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new products. No new emissions are expected due to disposal of the new products; therefore, there would be no new disproportionate impacts on minority or low-income populations.

7.6. Cumulative Impacts

A major existing environmental consequence of the use of the new products is littering of discarded used cigarettes. However, the cumulative impact from discarded cigarettes is declining because the use of cigarettes in the United States is declining.

As for the glass matt component in the heat source assembly, it can persist in the environment, but is inert and would be a small fraction of waste as compared to the total waste disposed of in the United States.

…ative would not change the existing condition of disposal of all cigarettes and cigarette packaging, as many combusted tobacco products would continue to be marketed.

8. L… eparers

The following i… als were primarily responsible for preparing and reviewing this programmatic environmental … ment (PEA):

Preparers:

Ronald L. Edwards Jr., M.S., Center for Tobacco Products
Education: M.S. in Biology
Experience: 24 years in environmental regulation and laboratory toxicology
Expertise: Heavy metal analysis, water quality, environmental remediation, FDA, EPA, and USDA investigator

Reviewer:

Hoshing W. Chang, Ph.D., Center for Tobacco Products
Education: M.S. in Environmental Science and Ph.D. in Biochemistry
Experience: 10 years in NEPA practice
Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

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EXAMPLE EA (CONTINUED)

Agency consulted

Not applicable.

References

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Confidential Appendix

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Compar[illegible]tween the New Products and the Predicate Product Relevant to the Environmental Assessmen[illegible]

STN	Component	Change
SE0014221	Tobacco	Decreased total mass
	Tobacco Blend	Decreased [redacted] Increased [redacted] Added [redacted]
	Heat Source	Removed [redacted] in the heat source mix
	Tobacco Roll Rod	Added [redacted] in the tobacco roll rod (TBR) and substrate (SUB) sections
	SUB section	Added [redacted] into tobacco beads in the SUB section
	Ingredients	Added two complex flavor ingredients [redacted] Removed three complex flavor ingredients [redacted]
	Characterizing flavor	Increased menthol
SE0014246	Tobacco	Decreased total mass
	Tobacco Blend	Increased [redacted] Added [redacted]
	Heat Source	Shortened tobacco rods Increased substrate rod density Removed [redacted] in the heat source mix
	Tobacco Roll Rod	Added [redacted] tobacco
	SUB section	Longer combined filter and shorter tobacco SUB and TBR
	Ingredients	Increased [redacted] Removed menthol
	Characterizing flavor	Removed menthol

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Center for Tobacco Products Contact Center

- Website: www.fda.gov/tobaccoproducts
- Phone: 877-287-1373
- E-mail: AskCTP@fda.hhs.gov