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LIST OF ABBREVIATIONS

Abbreviation	Definition
CFR	Code of Federal Regulations
EA	Environmental Assessment
ENDS	Electronic Nicotine Delivery System
EPE	expanded polyethylene
FDA	Food and Drug Administration
FONSI	Finding of No Significant Impact
NEPA	National Environmental Policy Act of 1969
PMTA	Pre-Market Tobacco Application
SKU	stock keeping unit
U.S.	United States
w/w	weight by weight

1 EXECUTIVE SUMMARY

The Environmental Assessment (EA) has been prepared for the Proposed Action (manufacturing, use, and disposal of NJOY ACE products) in accordance with 21 Code of Federal Regulations (CFR) 25.20 and 25.40 and the United States (U.S.) Food and Drug Administration (FDA) and Council on Environmental Quality regulations implementing the National Environmental Policy Act of 1969 (NEPA). The EA is being submitted as part of the NJOY ACE Pre-Market Tobacco Application (PMTA). The format and content of the EA adhere to FDA's guidance (FDA 1998, 2015, 2019a, 2019b). The overall conclusion from the assessment is that there are no significant environmental risks, and a Finding of No Significant Impact (FONSI) for this EA of NJOY ACE products by FDA is warranted.

A complete EA is provided in Module 7.11 for each of the 10 NJOY ACE stock keeping units (SKUs) as outlined below. All 10 SKUs are listed in Table 2.

The organization of environmental assessments for each of the 10 SKUs within Module 7 is listed below.

- 7.1 Need for the Proposed Actions
- 7.2 Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products
- 7.3 Potential Environmental Impacts of the Proposed Actions and Alternatives – Use of the New Products
- 7.4 Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Products
- 7.5 Mitigation of Environmental Effects
- 7.6 Alternatives to the Proposed Actions
- 7.7 List of Preparers
- 7.8 Listing of Agencies and Persons Consulted
- 7.9 Other Documents Relating to Research [911(d)(5)] or [910(b)(1)]
- 7.10 Referenced Literature References
- 7.11 Environmental Impact Appendices
  - Report
  - Appendix A: (b)(4) [redacted]
- 7.12 Environmental Assessment Confidential Appendices (marketing projections for (b)(4) [redacted] years)

For ease of review, Table 1 provides a direct link to the full Environmental Assessment report for each of the 10 SKUs in Module 7.11.

Table 1 Location of Environmental Assessment Report For Each of the 10 SKUs

Module 7.11 NJOY ACE Device (b)(4) Environmental Assessment
Module 7.11 NJOY ACE POD (b)(4) Environmental Assessment
Module 7.11 NJOY ACE POD (b)(4) Environmental Assessment
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Module 7.11 NJOY ACE POD (b)(4) Environmental Assessment

2 APPLICANT DETAILS

The EA was prepared in accordance with 21 CFR 25.40 and CFR 25.20.

The applicant (NJOY, LLC [NJOY]) is seeking marketing authorization for its ACE Electronic Nicotine Delivery System (ENDS) products. One approved product, NJOY ACE POD (b)(4) stock keeping unit [SKU] (b)(4) would be introduced into interstate commerce for commercial distribution in the U.S. The other approved products (9 SKUs) would be maintained on the market for sale and distribution in the U.S.

> Applicant Name: NJOY, LLC

> Applicant Address: (b)(6)

> Applicant Contact: (b)(6)

> Manufacturing Address: (b)(4) (b)(6) China (b)(6)

E-liquids are manufactured at (b)(4) in the U.S.; (b)(4) and sales in the U.S. Product manufacturing flow is discussed in greater detail for each SKU in Module 7.2.

3 PRODUCT INFORMATION

3.1 Product Name: NJOY ACE

NJOY ACE product is a closed ENDS that heats an e-liquid to yield an inhalable aerosol. The NJOY ACE system consists of the NJOY ACE Device and the 9 NJOY ACE PODS products subject to this PMTA. The NJOY ACE device is sold separately from the NJOY ACE PODS, which are sold as packs consisting of 2 pods of the same flavor and strength.

The NJOY ACE product e-liquid is manufactured in two nicotine concentrations (2.4% weight by weight [w/w] and 5%w/w nicotine) and contains (b)(4)

The NJOY ACE product falls under the category of an ENDS product. The product is a "new tobacco product" under Section 910(a)(1) of the Federal Food, Drug, and Cosmetic Act, as it was not commercially marketed in the U.S. as of 15 February 2007.

3.2 Product Identification

Product Category: Electronic Nicotine Delivery System (ENDS)

Product Subcategories: ENDS/closed E-cigarettes (for Device)

ENDS/e-liquid (for PODS)

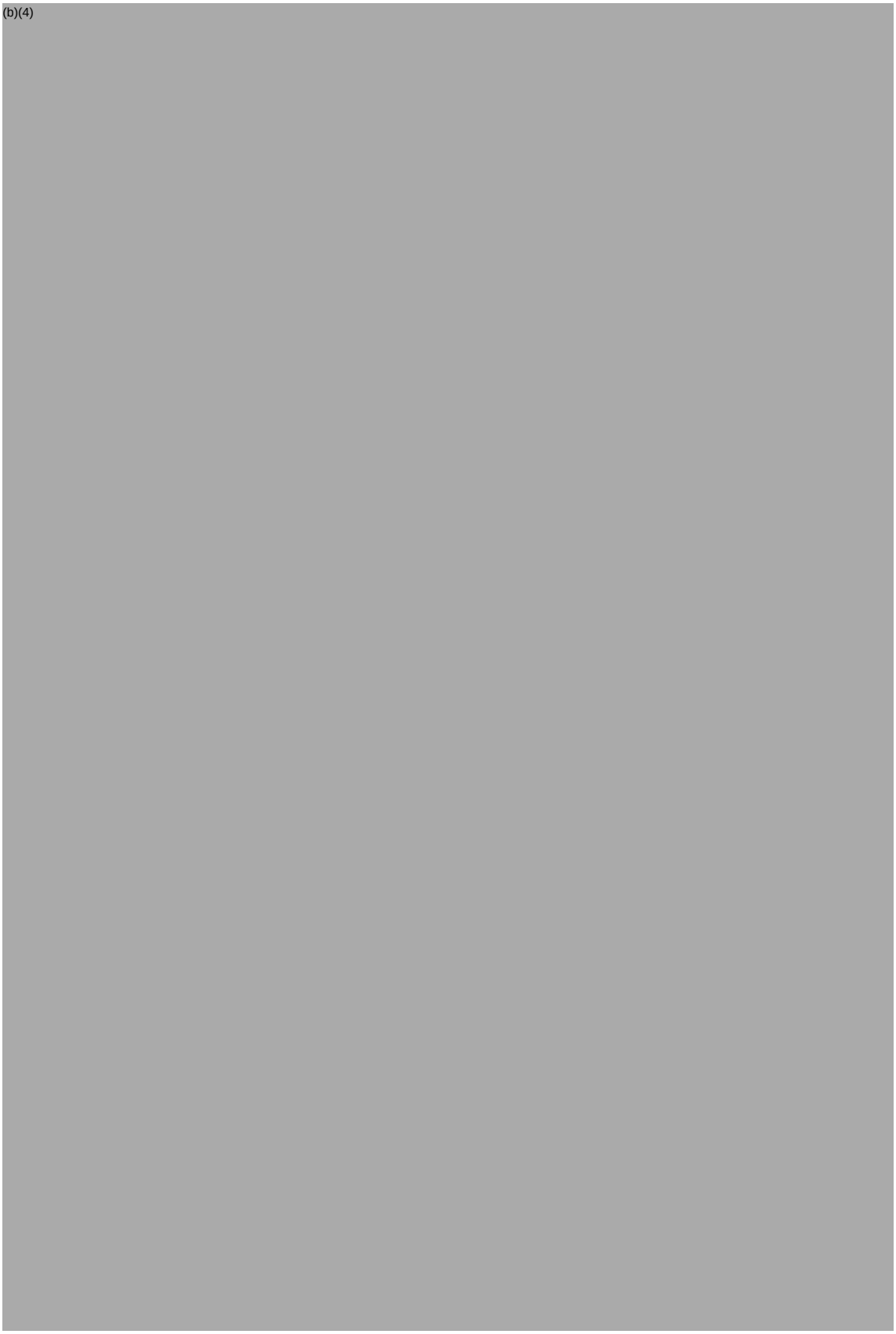
3.2.1 NJOY ACE Device

NJOY ACE Device (SKU (b)(4) Figure 1 and Figure 2) is a closed ENDS that heats an e-liquid to yield an inhalable aerosol. The NJOY ACE Device includes a rechargeable, (b)(4) battery cell (which cannot be adjusted by the user) and a universal serial bus cable.

Figure 1 NJOY ACE Device

Figure 2 NJOY ACE Device - Schematic

(b)(4)



3.2.2 NJOY ACE PODS

The NJOY ACE pod (Figure 3 and Figure 4) is a sealed, pre-filled, non-refillable, disposable container closure system that contains the heating element for the e-liquid. The NJOY ACE device is sold separately from the NJOY ACE PODS. The pods are manufacturer filled with 1.9 milliliters of e-liquid.

Figure 3 NJOY ACE POD

(b)(4)

Figure 4 NJOY ACE POD – Schematic

(b)(4)

3.2.3 NJOY ACE Product Packages

(b)(4)

The packaging material in direct contact with the NJOY ACE PODS consists of a (b)(4) Details regarding these materials and the packaging process are available in Module 7.2 for each SKU.

Figure 5 NJOY ACE Device – Packaging Image

(b)(4)

Figure 6 NJOY ACE Device – User Guide

(b)(4)

Figure 7 NJOY ACE POD (b)(4) (as example) – Packaging Image

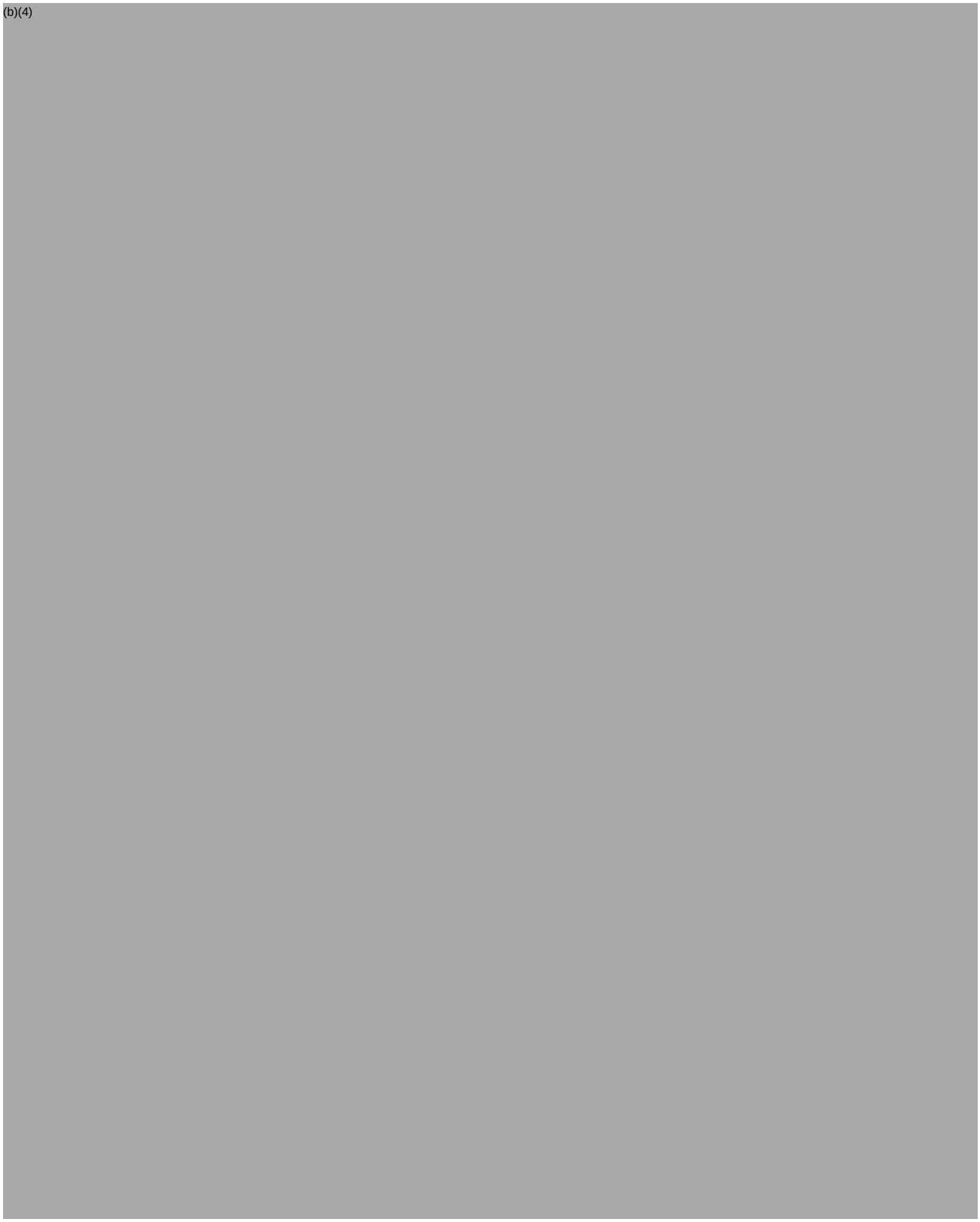
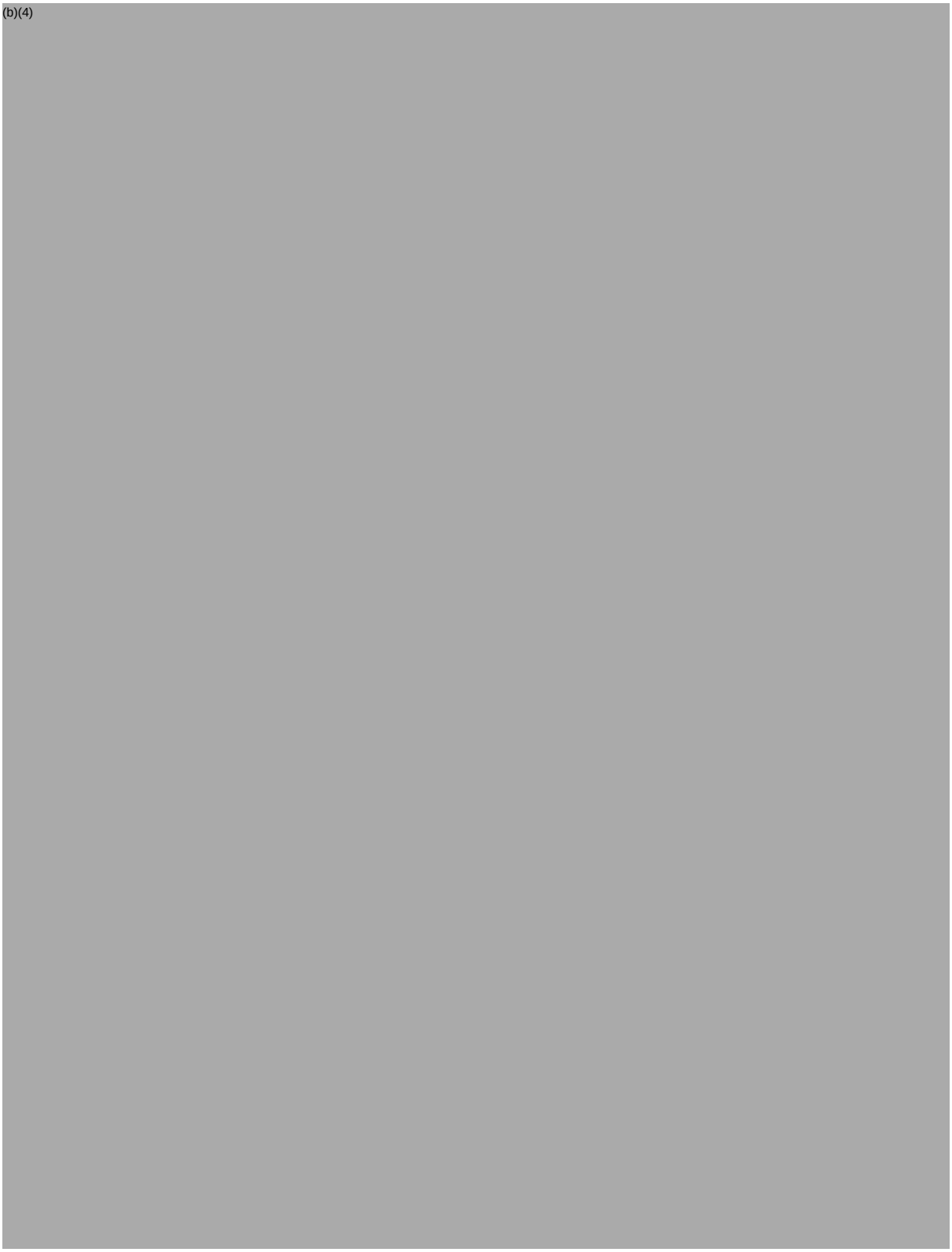
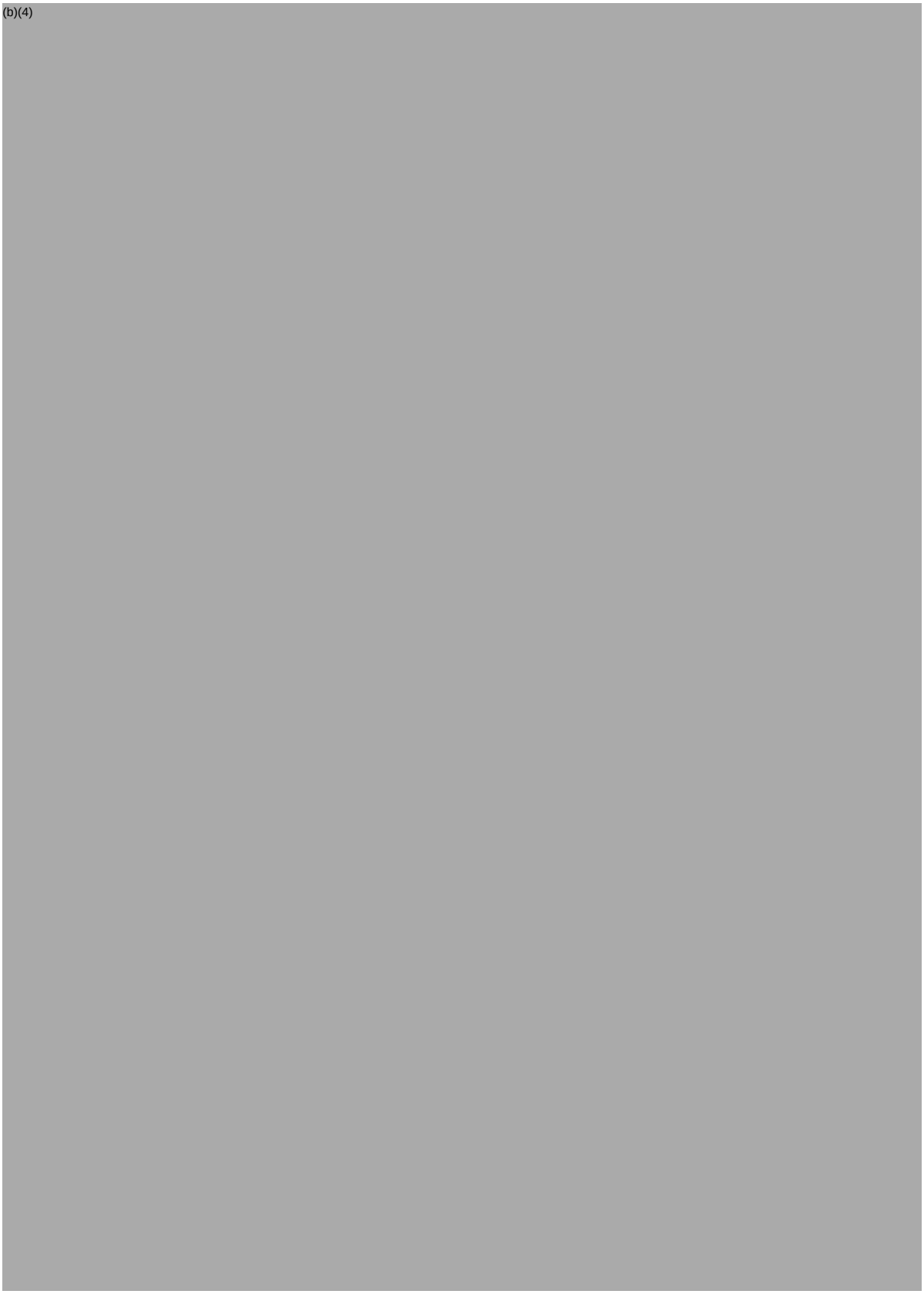


Figure 8 NJOY ACE POD – Product Insert

(b)(4)



(b)(4)



4 REQUESTED APPROVAL

NJOY seeks marketing authorizations that would permit continued marketing in interstate commerce of 9 NJOY ACE ENDS product SKUs under the provisions of Sections 910 and 905 of the Federal Food, Drug, and Cosmetic Act (Table 2).

Table 2 Product SKUs – NJOY ACE Device and Pods

Product	SKU
(b)(4)	

In addition, the applicant seeks a marketing authorization to introduce the following NJOY ACE ENDS SKU into interstate commerce for commercial distribution in the U.S.: NJOY ACE PODS (b)(4) SKU: (b)(4)

Confidential marketing projections for the NJOY ACE product for the (b)(4) years are presented in Module 7.12, Marketing Projections for NJOY ACE for each of the 10 SKUs.

5 PURPOSE AND NEED

The need for the Proposed Action, requested by the applicant, is for the FDA to issue a marketing order for each of the 9 currently marketed SKUs (Table 2) after finding the new tobacco products would be appropriate for the protection of public health. The applicant wishes to introduce the ACE products into interstate commerce for commercial distribution in the U.S. In addition, the applicant seeks a marketing authorization to introduce the following NJOY ACE ENDS SKU into interstate commerce for commercial distribution in the U.S.: NJOY ACE PODS (b)(4) SKU: (b)(4)

The FDA shall review the PMTA, assess the Proposed Action, and subsequently determine whether or not to issue a marketing order for the NJOY product as a statutory requirement under section 910(c) of the FD&C Act.

The Proposed Action would provide an alternative to combustible cigarettes.

6 ALTERNATIVES

Potential alternatives were evaluated in the EA as required by Section 102(2)E of NEPA. The Proposed Action, or Proposed Action Alternative (ACE device and pods), and the No Action Alternative were compared to determine potential environmental impacts. The No Action Alternative is represented by no FDA approval and authorized marketing order for the Proposed Action in the U.S.

7 IDENTIFICATION AND CHARACTERIZATION OF INGREDIENTS OF INTEREST

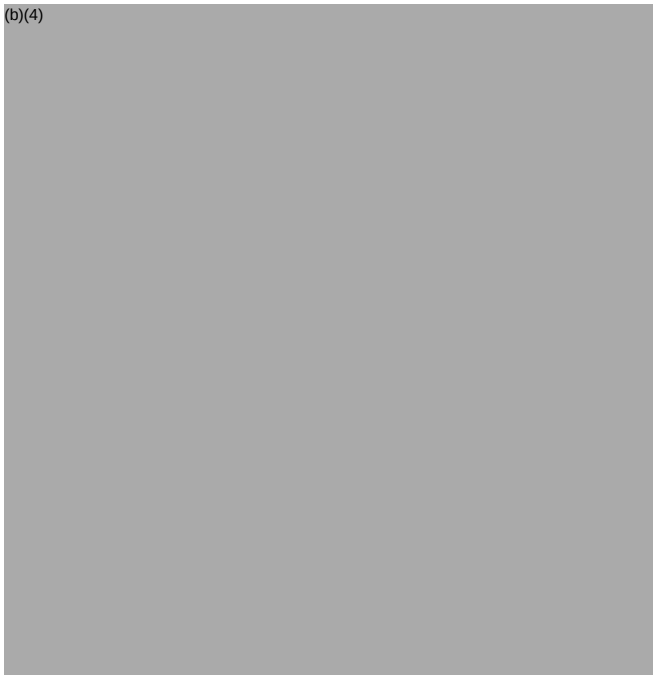
The process and results for the identification of ingredients contained in the Proposed Action products that were carried forward for evaluation in the EA are described in detail in the EA report (Module 7.11, Section 6, for each of the 10 SKUs; see links in Table 1). The selected ingredients were considered in potential discharge/spill release scenarios, and modeling was undertaken to determine estimated concentrations that could occur in the environment if a release were to occur. The results were then included in the environmental impacts assessment (Module 7.11, Section 7, for each of the 10 SKUs; see links in Table 1).

8 POTENTIAL ENVIRONMENTAL IMPACTS OF THE PROPOSED ACTION ALTERNATIVE AND THE NO ACTION ALTERNATIVE

Potential environmental introductions resulting from manufacturing, use, and disposal were evaluated for the Proposed Action and No Action Alternative. A description of the affected environment (existing conditions) and environmental impacts from the Proposed Action and the No Action Alternative is provided in the environmental impacts assessment (Module 7.11, Section 7.1, for each of the 10 SKUs; see links in Table 1).

The potential environmental impacts due to manufacturing were assessed at manufacturing facilities (including facilities outside of the U.S.). Waste generated at these facilities and its release into air, wastewater, and solid waste streams were characterized. Regulatory compliance information was provided by the applicant and its vendors. Compliance audits and inspections were not conducted as part of this assessment.

The potential environmental impacts associated with manufacture, use, and disposal of ACE products under the Proposed Action were evaluated for the following subjects (Module 7.11, Section 7.2, for each of the 10 SKUs; see links in Table 1):



9 CUMULATIVE IMPACTS

The effects on the environment that result from the incremental effect of the Proposed Action, when added to other past, present, and reasonably foreseeable future actions, were assessed. Other comparable products currently on the market represent present actions; those products that have been marketed and sold in the past but are not longer available to consumers represent past actions; and comparable products that will likely be on the market in the future represent reasonably foreseeable future actions.

Overall, no adverse cumulative effects are anticipated as a result of the Proposed Action in combination with other past, present, or reasonably foreseeable future actions. There were no actions identified that, when considered with product manufacturing, use, and disposal under the Proposed Action, would lead to cumulative impacts.

The incremental impacts from the Proposed Action do not contribute significantly to the overall cumulative impacts from other actions (past, present, or reasonably foreseeable future actions).

10 MITIGATION MEASURES

During the review of the available information and the impact assessment, it was determined that no adverse environmental effects would occur due to the manufacture, use, and disposal of the Proposed Action products; thus, no mitigation measures are required. Manufacturing facility best management practices, including regulatory compliance measures and emergency response plans, would be sufficient to prevent adverse impacts to environmental resources.

The overall conclusion from the assessment is that there are no significant environmental impacts, and a FONSI for this EA of NJOY ACE PODS and devices products by FDA is warranted.

11 REFERENCES

FDA 1998. Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications. U.S. Department of Health and Human Services, FDA, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER). CMC 6, Revision 1. July.

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FDA. 2019a. Premarket Tobacco Product Applications and Recordkeeping Requirements. Proposed Rule. U.S. Department of Health and Human Services. 21 CFR 1100, 1107, 1114. 84 FR 50566. September 25.

FDA 2019b. Deemed Tobacco Product Applications - A Public Meeting. October 28–29, 2019. Available at: https://www.fda.gov/tobacco-products/ctp-newsroom/deemed-tobacco-product-applications-public-meeting-10282019-10292019. Accessed February 2020.