Environmental Assessment for the Marketing Order for NJOY DAILY (b)(4)

(b)(4)

Document Certification

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of NJOY, LLC.

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NJOY, LLC

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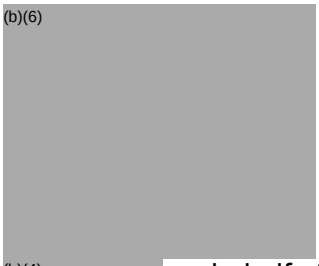

(b)(4) on behalf of NJOY, LLC

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Document Information

Report Title	Environmental Assessment for the Marketing Order for NJOY DAILY (b)(4)
Prepared for	Center for Tobacco Products U.S. Food and Drug Administration
Date	(b)(4)

Prepared by:
(b)(4)
(b)(6)

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Confidential Appendix

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1 Executive Summary

The Environmental Assessment (EA) has been prepared for the Proposed Action (manufacturing, use, and disposal of NJOY DAILY Electronic Nicotine Delivery System [ENDS] product; NJOY DAILY (b)(4) Stock Keeping Unit [SKU] (b)(4) 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 (CEQ) regulations implementing the National Environmental Policy Act of 1969 (NEPA). The EA is being submitted as part of the NJOY DAILY Pre-Market Tobacco Application (PMTA). The format and content of the EA adhere to FDA's guidance (FDA 1998, 2015, 2019a, 2019b, 2020). The overall conclusion from the assessment is that there are no significant environmental risks associated with the manufacture, use, and disposal of NJOY DAILY (b)(4)

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2 Applicant Details and Description of Proposed Action

The Applicant (NJOY, LLC [NJOY]) is seeking marketing authorization for one of its NJOY DAILY. The product would be maintained on the market for sale and distribution in the United States.

- **Applicant Name:** NJOY, LLC
- **Applicant Address:** (b)(6)
- **Applicant Contact:** (b)(6)
- **Manufacturing Address:** (b)(4) (b)(6)

2.1 Product Name: NJOY DAILY (b)(4)

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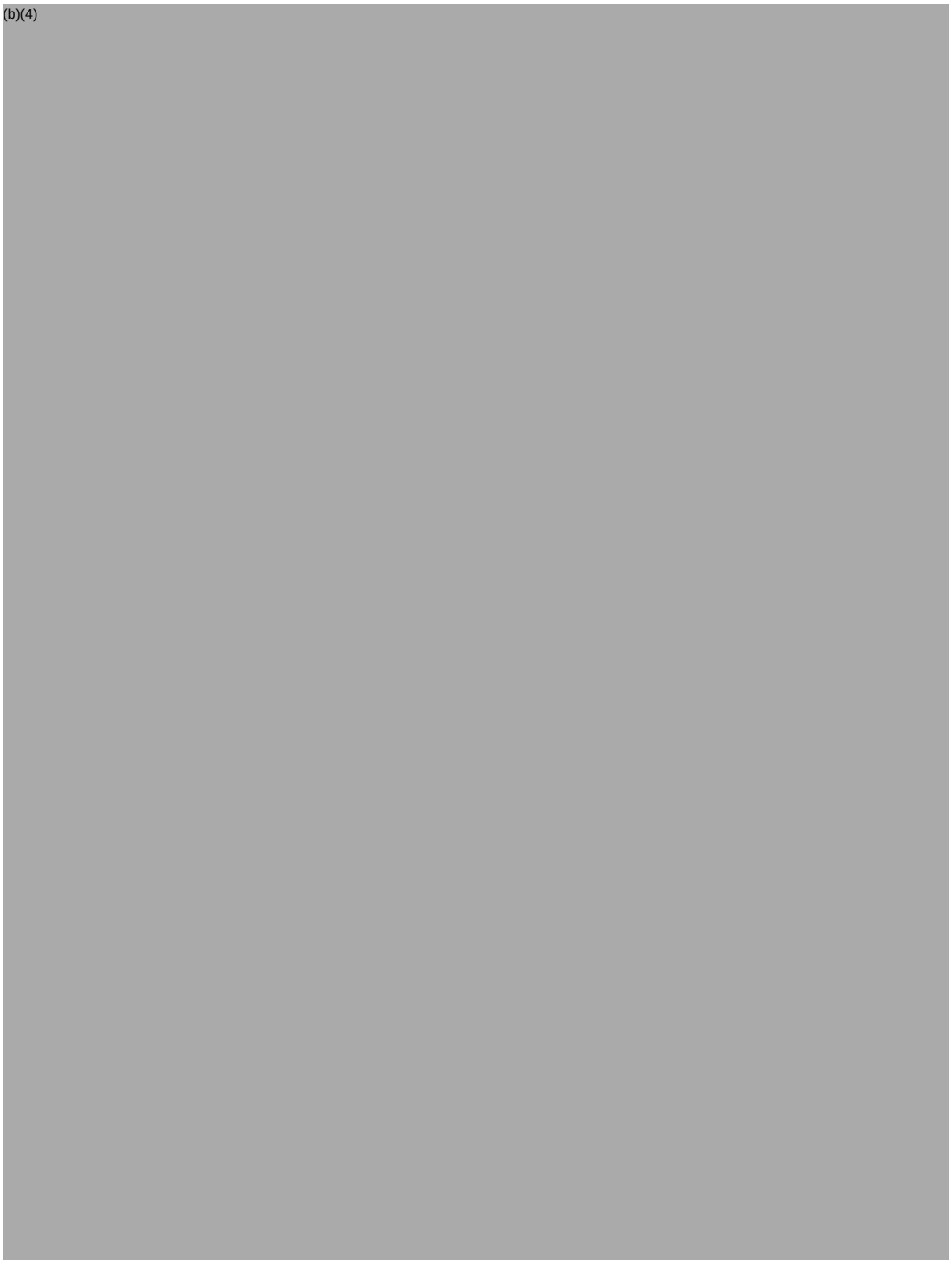

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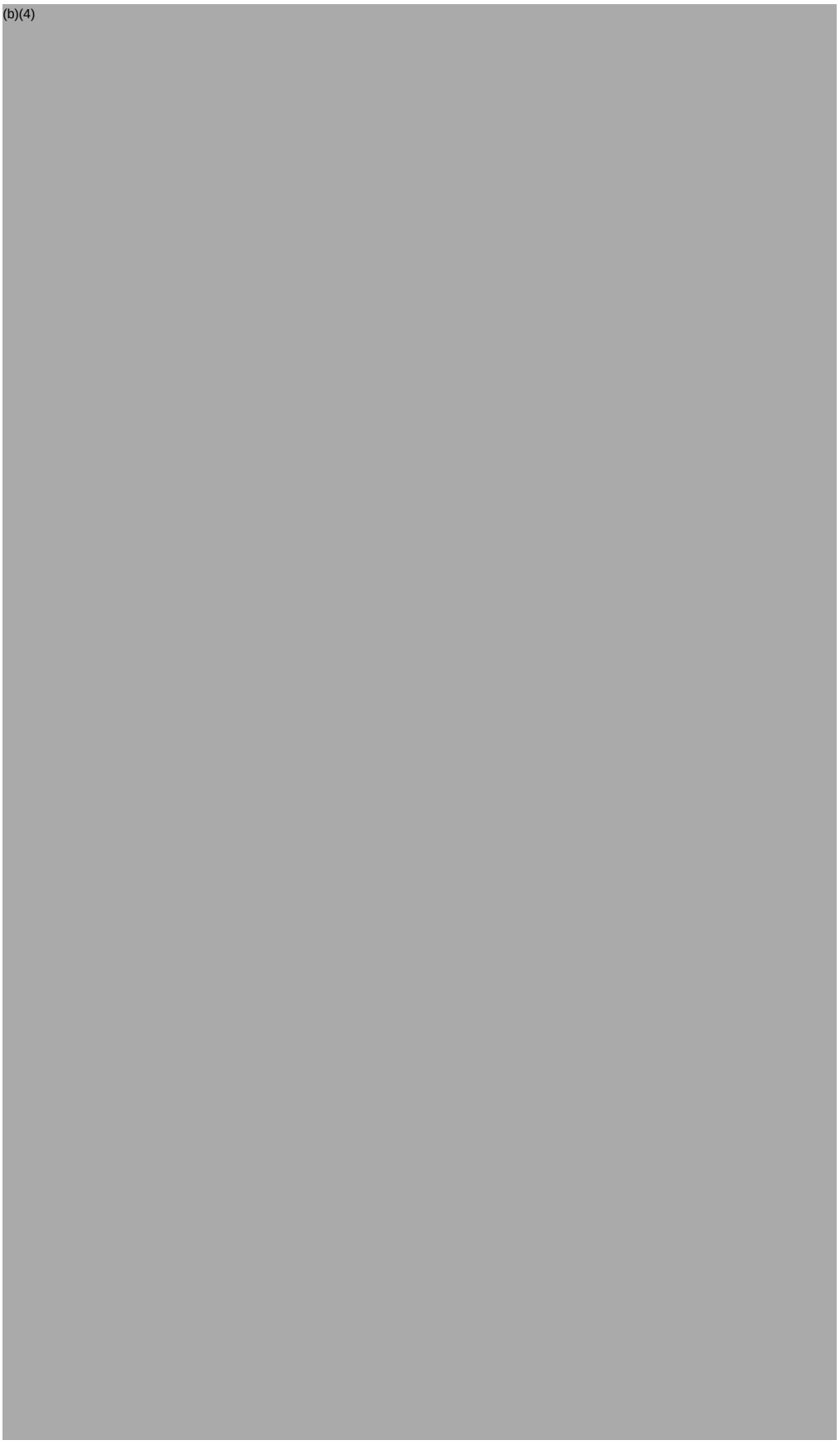

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3 Requested Action

NJOY seeks a marketing order that would permit NJOY's continued marketing in interstate commerce of NJOY DAILY (b)(4) (SKU (b)(4)

Confidential marketing projections for NJOY DAILY for marketing years (b)(4) are presented in the Confidential Appendix (Section A).

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4 Purpose and Need

The need for the Proposed Action, requested by the Applicant, is for the FDA to issue a marketing authorization order for NJOY DAILY (b)(4) (SKU (b)(4) after finding the new tobacco product would be appropriate for the protection of public health.

The FDA shall review the PMTA, assess the Proposed Action as described in the previous paragraph, 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.

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5 Alternatives

Potential alternatives were evaluated in the EA as required by Section 102(2)E of NEPA. The Proposed Action, or Proposed Action Alternative (NJOY DAILY (b)(4) and the No Action Alternative were compared to determine potential environmental impacts. The No Action Alternative is represented by no FDA authorized marketing order for the Proposed Action product in the United States.

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6 Identification and Characterization of Ingredients of Interest

This section describes the process and results for the identification of ingredients contained in the Proposed Action product that were carried forward for evaluation in the EA. 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 of Section 6 were included in the environmental impacts assessment (Section 7).

6.1 Screening of Chemicals and Potential Release Scenarios

6.1.1 Process for Selection of Chemicals to Evaluate in the EA

(b)(4)

As summarized in Figure 4, the ingredient screening for the EA consisted of three parts. In Part I, the (b)(4) program (EPA 2017) was used to gather lethal median concentration (LC_{50}[1]; lethal concentration resulting in mortality of 50 percent of sample of a specific test-animal population), effective median concentration (EC_{50}; concentration of a substance in an environmental medium expected to produce a certain effect in 50 percent of test organisms), and chronic values (ChV) for various species; these values are used to derive an average normalized toxicity value. In Part II, the percentage composition of ingredients in the product was used to derive the average normalized relative toxicity values. Ingredients with low average normalized relative toxicity values (deemed more toxic) were then selected for the screening level risk assessment using the U.S. Environmental Protection Agency (EPA) (b)(4) model, which is considered by the EPA to be a conservative estimate of risk (Part III).

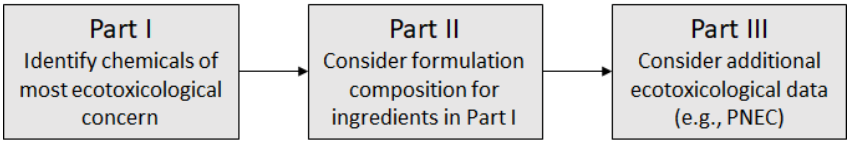

Figure 4. Overview of environmental assessment screening standard operating procedure.

6.1.1.1 Part I – Identification of Chemicals of Potential Ecological Concern

(b)(4) is a predictive ecotoxicity tool provided by the EPA. It is predictive software that estimates the acute and chronic aquatic toxicity for aquatic organisms, such as plants, fish, and invertebrates. Below are the (b)(4) values for the ingredients.

1. **Median Lethal Concentration (LC_{50}):**

Several LC_{50} values are reported and include fish (96-hour), fish (salt water [SW], 96-hour), Daphnid (48-hour), mysid (96-hour), mysid (SW, 96-hour), earthworms (14 days), green algae (SW, 96-hour), and mysid (SW, 48-hour).

[1] LC_{50} values are a common ecological benchmark concentration used in (b)(4)

2. **Median Effective Concentration (EC_{50}):**

Two EC_{50} values are typically reported, green algae (96-hour) and *Lemna gibba* (7-day).

3. **Chronic Value (ChV):**

The ChV is the concentration of a chemical at which adverse effects are observed as a result of long-term exposure to the chemical. The ChV is calculated as follows:

$$ChV = 10^{\left(\left[\frac{\log[(LOEC\ x\ NOEC)]}{2}\right)\right]}$$

where LOEC is the lowest observed effect concentration and NOEC is the no-observed-effect concentration.

ChV is available for several species including fish, Daphnid, green algae, fish (SW), and mysid (SW). The available values were used to derive an average normalized toxicity value for each ingredient.

Conservative benchmark toxicity values, representing the minimum value among the species with benchmark toxicity values for LC_{50}, EC_{50}, and ChV, were obtained from the (b)(4) program and selected for each chemical for further analysis (LC_{50} conservative (i), EC_{50} conservative (i) and ChV conservative (i) below).The selected values were rescaled to values between 0 and 1, with 0 corresponding to chemicals that are considered to be the most toxic. The normalized LC_{50}, EC_{50}, and ChV values were calculated as follows:

$$Normalized\ LC_{50}\ (i,j) = \frac{LC_{50\ conservative\ (i)} - LC_{50\ minimum\ (j)}}{LC_{50\ maximum(j)} - LC_{50\ minimum(j)}}$$

$$Normalized\ EC_{50}(i,j) = \frac{EC_{50\ conservative\ (i)} - EC_{50\ minimum(j)}}{EC_{50\ maximum(j)} - EC_{50\ minimum(j)}}$$

$$Normalized\ ChV\ (i,j) = \frac{ChV_{conservative\ (i)} - ChV_{minimum(j)}}{ChV_{maximum(j)} - ChV_{minimum(j)}}$$

where *i* represents select chemical and *j* represents target species endpoints across chemicals. The conservative values were selected from a range of target species endpoints for the select chemical. The maximum and minimum toxicity values were obtained for each chemical and each target species endpoint.

The normalized LC_{50}, EC_{50}, and ChV values for each chemical were weighted equally to calculate a weighted normalized toxicity score that represents an overall toxicity of each chemical. These values are between 0 and 1, with 0 corresponding to chemicals that are considered to be the most toxic. The weighted normalized toxicity scores were calculated as follows:

$$Weighted\ Normalized\ Toxicity = \left(\frac{1}{3} \times Normalized\ LC_{50}\right) + \left(\frac{1}{3} \times Normalized\ EC_{50}\right) + \left(\frac{1}{3} \times Normalized\ ChV\right)$$

6.1.1.2 Part II – Consideration of Ingredient Composition in Formulation

The percent composition (mass/mass [m/m]) of each ingredient was obtained from the manufacturer and used to estimate the concentration of each ingredient by assuming an e-liquid density of approximately 1.2 gram per milliliter (g/mL). The concentration is reported in units of milligrams per milliliter (mg/mL). Subsequently, the average normalized toxicity value was divided by the concentration of the ingredient to obtain the average normalized relative toxicity value. Ingredients with lower average normalized relative toxicity values are considered more toxic.

6.1.1.3 Part III – Consideration of Additional Ecotoxicological Data

The potential environmental impacts from ENDS use may occur at any point in the production flow, from raw ingredient manufacture through filling, distribution, use, and ultimately disposal. Potential release or discharge scenarios were developed (see Section 6.1.3 below and the Confidential Appendix [Section C]) to identify potential if unlikely routes of potential environmental impact. Chemicals identified in Part II as being of the likely greatest ecotoxicity were incorporated into those release or discharge scenarios (developed in part through interviews with the ENDS manufacturer and supporting vendors), and the environmental fate of the chemicals under those scenarios was derived using (b)(4) (EPA 2007). Several release or discharge scenarios were considered, and scenarios 1, 2, and 6 were evaluated using quantitative methods. The general (b)(4) modeling approach is summarized in Figure 5, and model output is discussed in Section 7.2 and included in the Confidential Appendix (Section B).

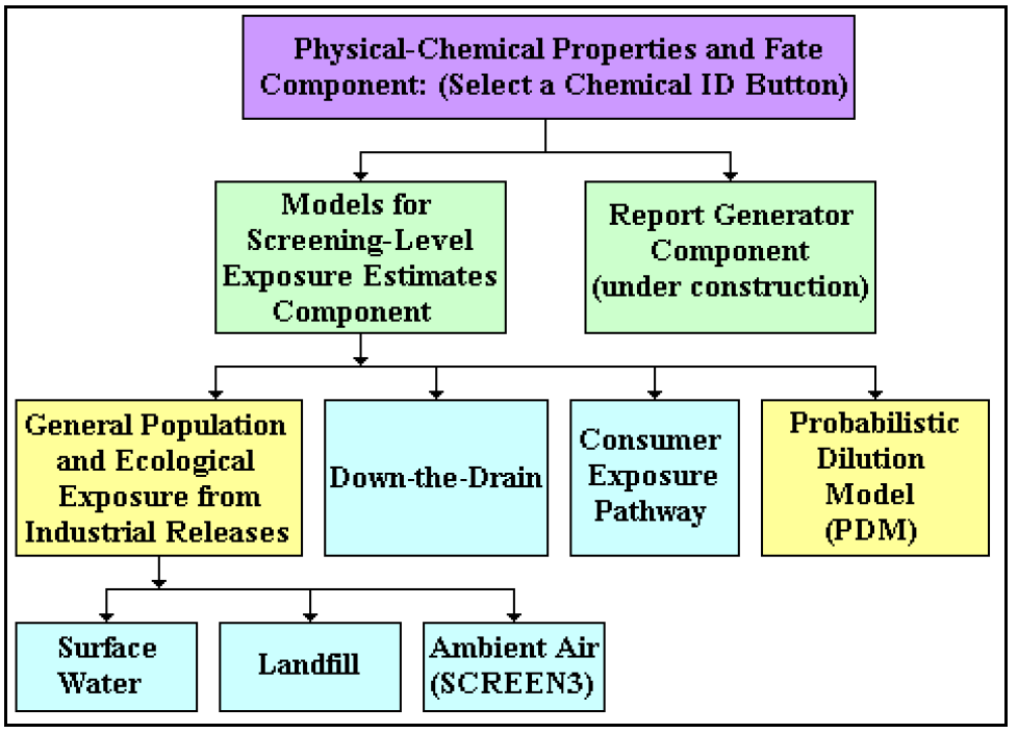

Figure 5. General (b)(4) modeling approach.

6.1.2 Chemicals Identified for Evaluation in the EA

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(b)(4)

6.1.3 Evaluation and Selection of Chemical Release Scenarios

Reasonable and plausible release scenarios of chemicals to air, water, and the terrestrial environment were evaluated and identified for each category, including: (1) manufacturing; (2) product use; and (3) disposal (Confidential Appendix [Section C]).

EICs for the aquatic, terrestrial, and atmospheric environments from manufacturing, use, and disposal (waste streams, liquid, and packaging) were estimated. FDA (1998: Section III.A.2) describes the method for calculating the EIC into the environment. Chemicals may enter the terrestrial environment when solids from wastewater treatment are applied to land, or direct discharges to the ground occur during manufacturing. Expected environmental concentrations (EECs; or predicted environmental concentrations [PECs]) were estimated for the chemicals carried forward into the EA. These estimates represent the potential exposure concentrations to ecological receptors in the environment. The factors used to calculate the EEC for each chemical/substance in aquatic, terrestrial, and air compartments are described below.

EECs were compared to ecological and human health toxicological benchmarks to determine whether there could be any potentially significant environmental impacts if a release of select chemicals were to occur, as discussed in Section 7.2 and the Confidential Appendix (Section D). Release scenarios for manufacturing surface water, manufacturing wastewater, and disposal end of life terrestrial soil were further evaluated as the most reasonable and appropriate in the EA.

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7 Potential Environmental Impacts of the Proposed Action Alternative and the No Action Alternative

The environmental issues section consists of a succinct description of the potential environmental introductions and effects, supported by information that may vary based on the type of Proposed Action Alternative. Potential environmental introductions resulting from manufacturing, use, and disposal were evaluated for the Proposed Action and No Action Alternative. This section provides a description of the affected environment (existing conditions) and environmental impacts from the Proposed Action and the No Action Alternative.

The potential environmental impacts due to manufacturing were assessed at manufacturing facilities. Waste generated at these facilities and its release to air, wastewater, and solid waste streams were characterized. Regulatory compliance information was provided by the Applicant and its vendors and is summarized in Section 7.1.1. Compliance audits and inspections were not conducted as part of this assessment.

The potential environmental impacts associated with manufacture, use, and disposal of NJOY DAILY under the Proposed Action were evaluated for the following subjects:

- Regulatory compliance
- Air quality
- Water resources
- Floodplains, wetlands, and coastal zones
- Land use and zoning
- Biological resources
- Geological features and soils
- Climate change
- Solid waste and hazardous waste
- Cultural resources
- Socioeconomics
- Environmental justice
- Public health and safety

7.1 Affected Environment

Environmental resources that may be affected by the alternatives are described below, along with a description of applicable regulations. The evaluation of environmental effects to these resources for each alternative is described in Section 7.2. A brief description of the existing resource conditions is provided herein.

Figure 6 presents a generalized illustration of the product flow from vendors to manufacturers, on to distribution, and ultimately to the consumer.

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7.1.1 Regulatory Compliance

Regulatory compliance is integral to the protection of environmental resources by employing institutional controls to avoid releases of potentially hazardous materials to the aquatic, terrestrial, and atmospheric compartments. A description of the Applicant's operations and environmental regulatory conditions for manufacturing is provided below.

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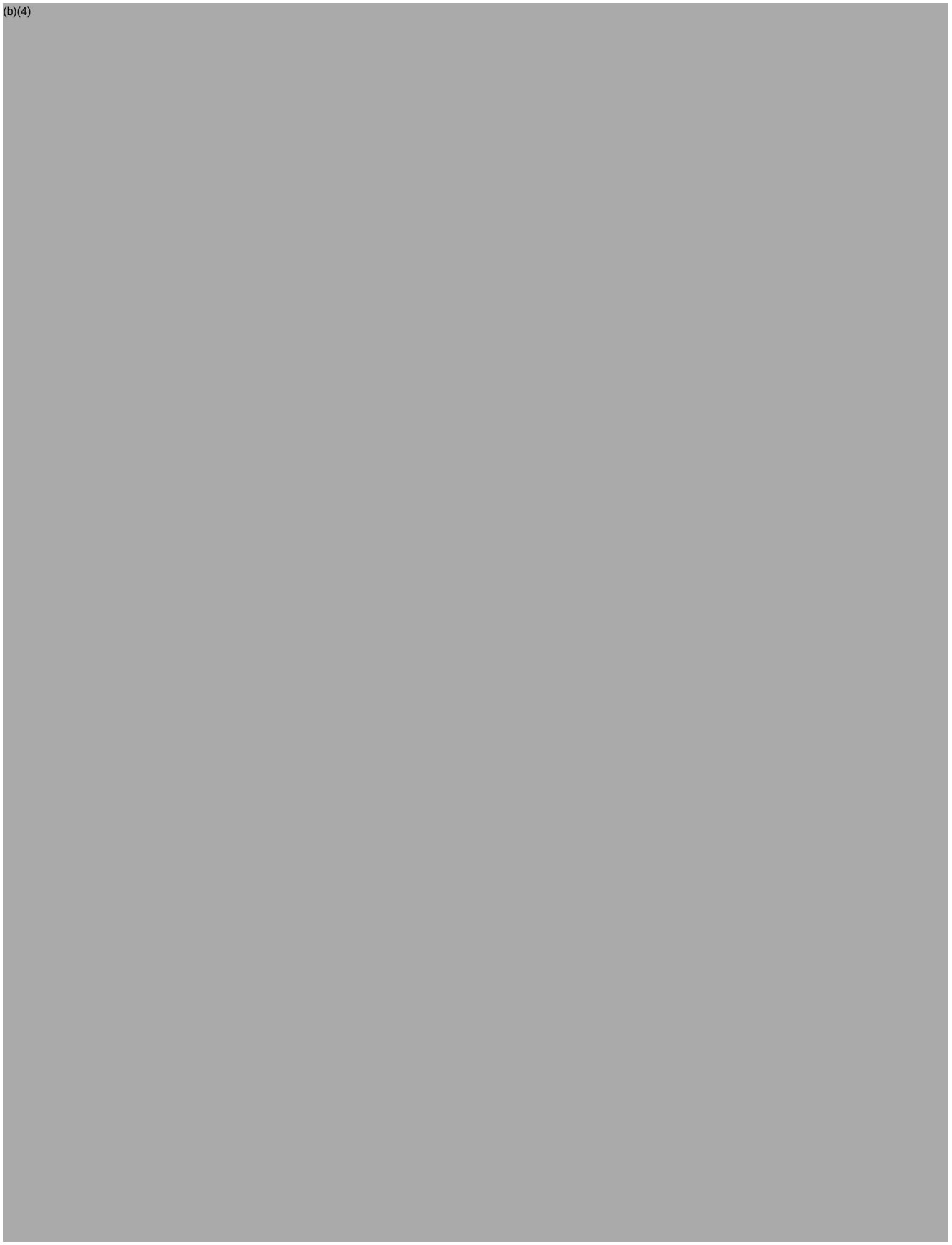

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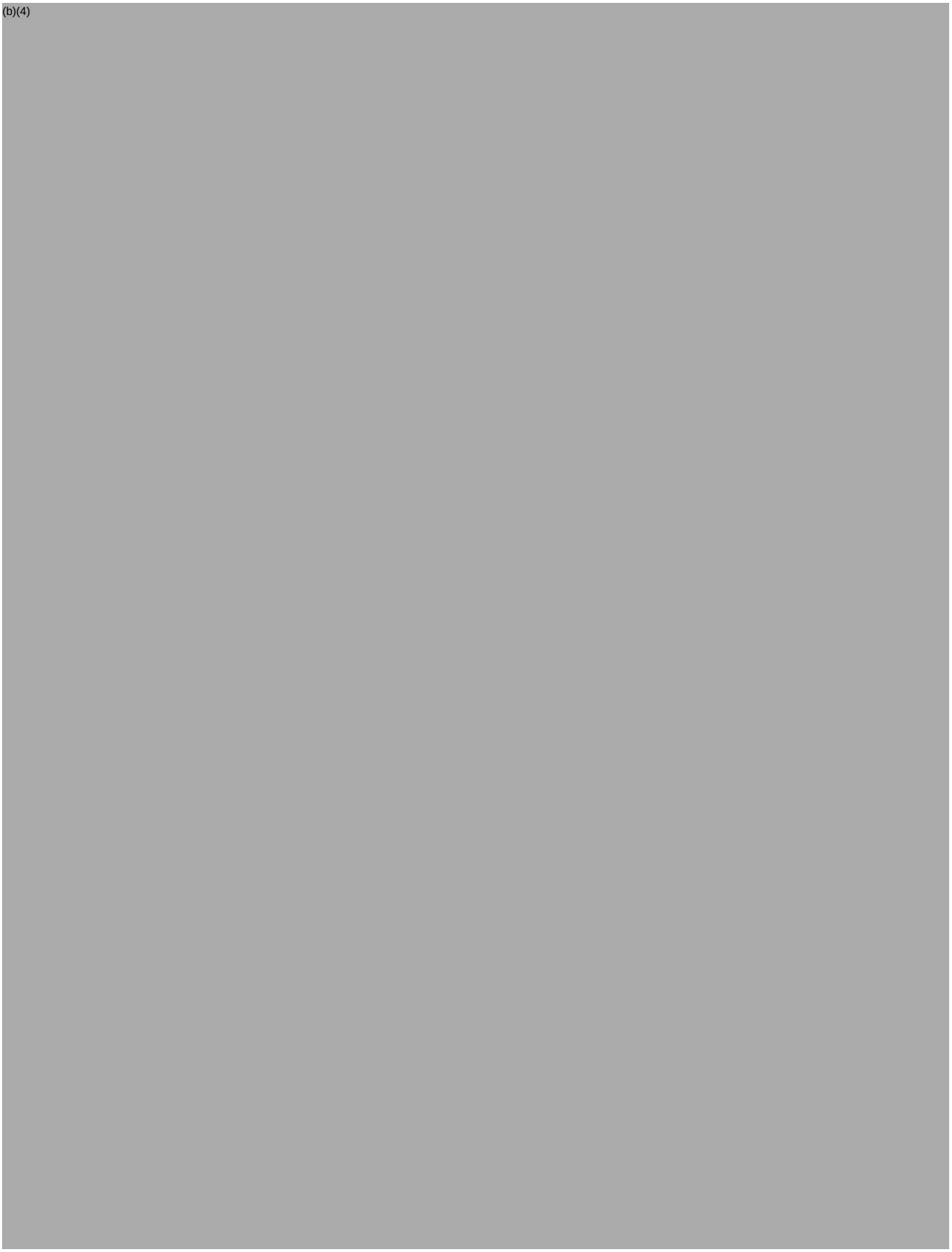

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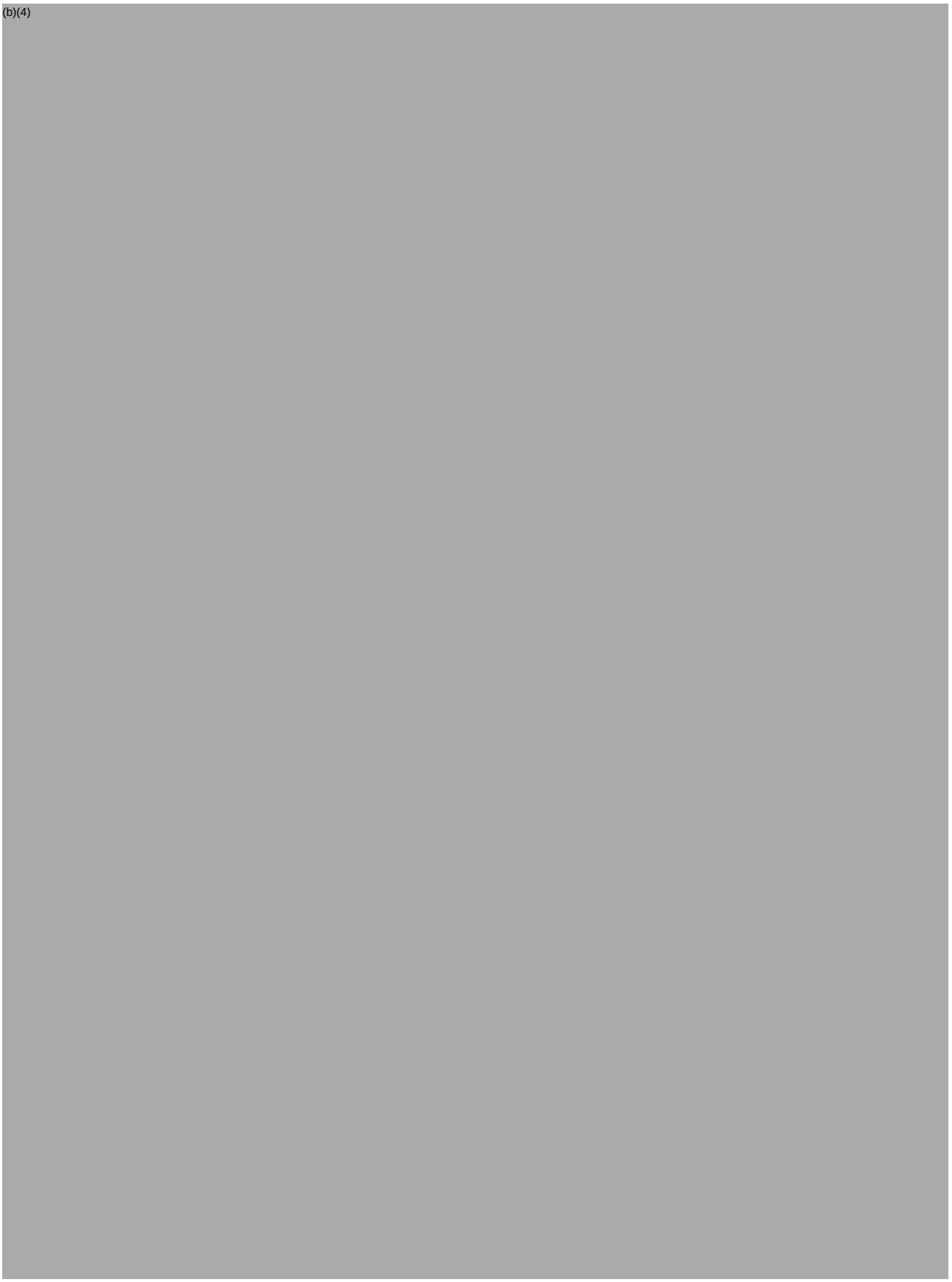

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7.1.2 Air Quality

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7.1.3 Water Resources: Floodplains, Wetlands (and Waters of the United States), and Coastal Zones

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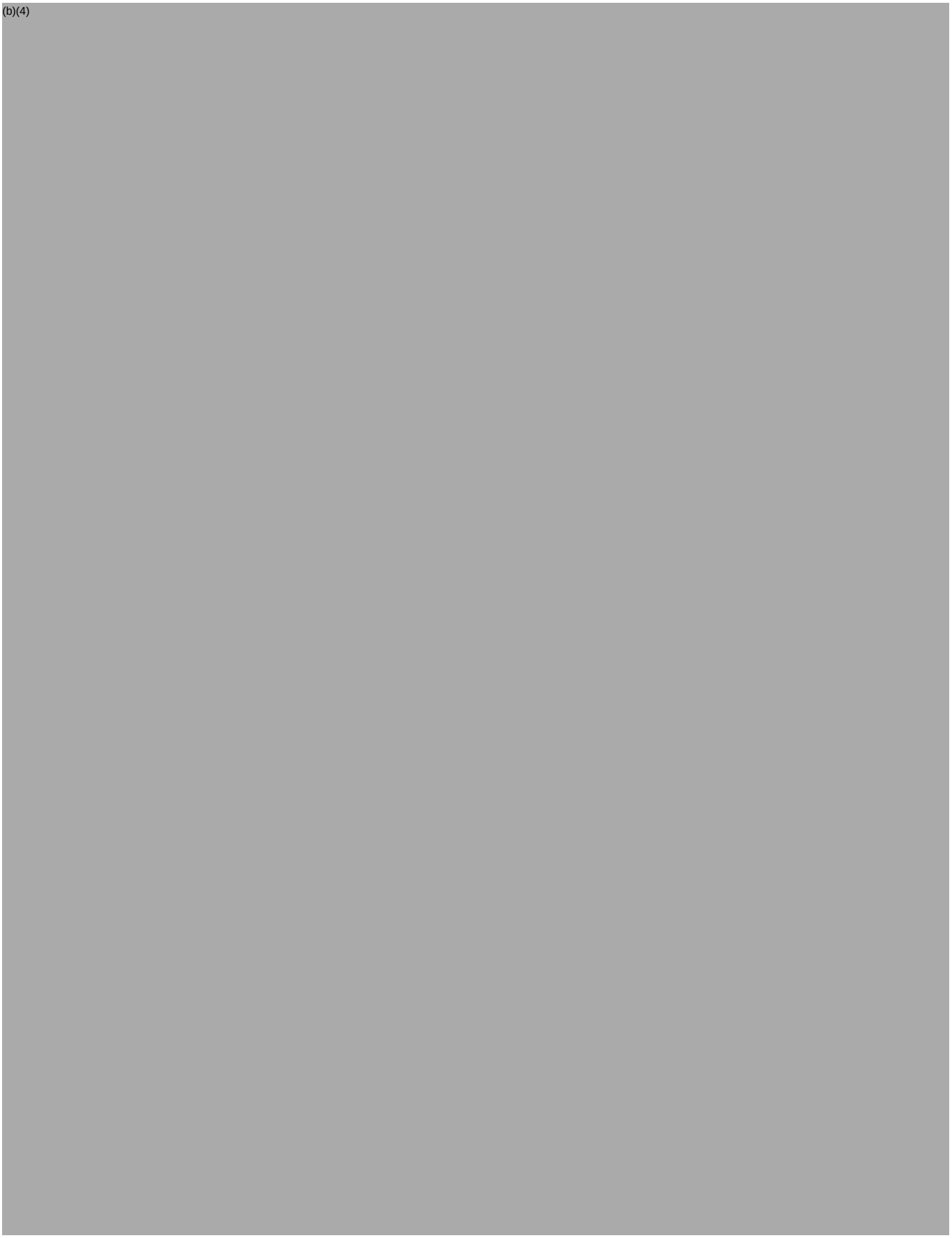

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7.1.4 Land Use and Zoning

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7.1.5 Biological Resources

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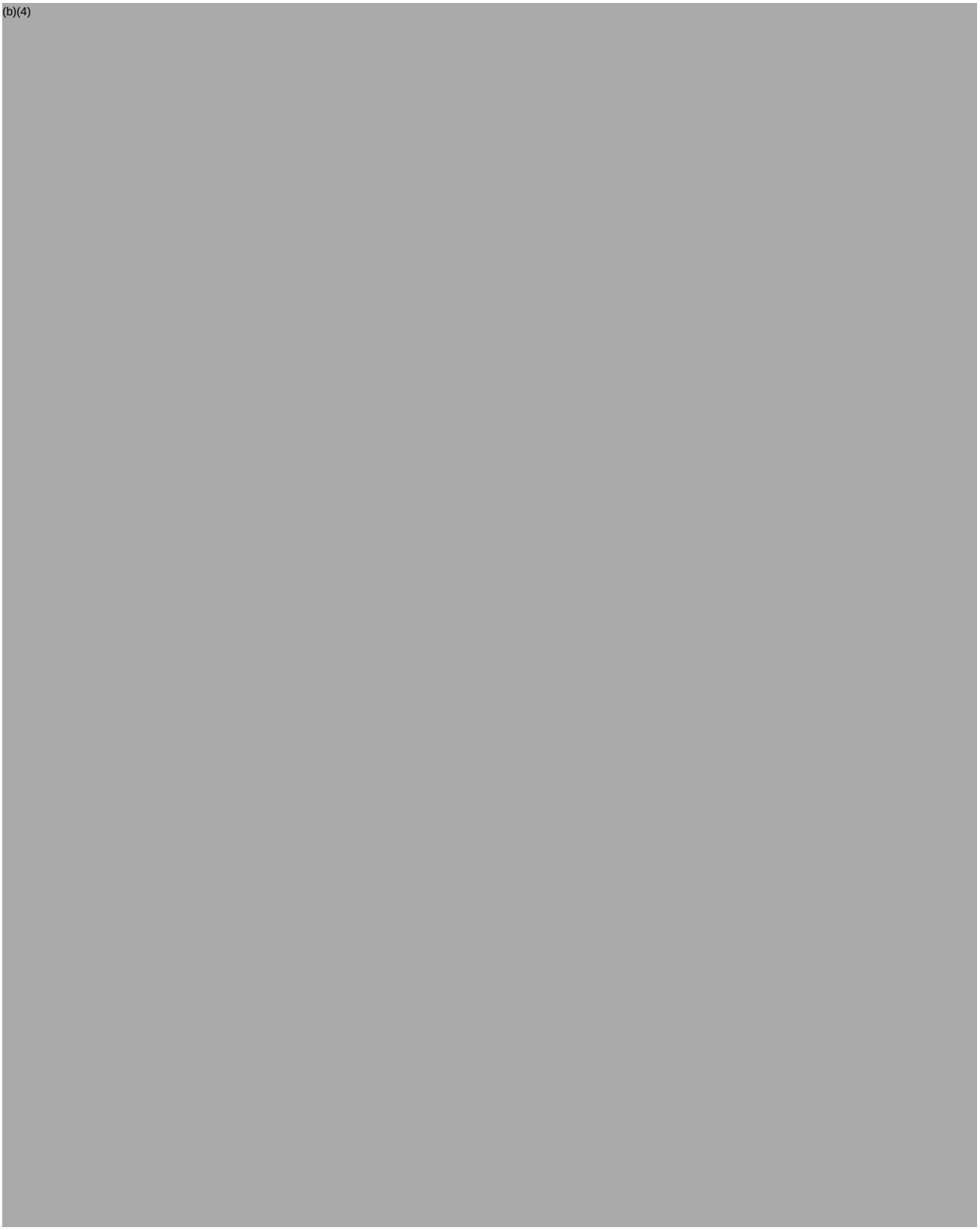

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7.1.6 Geological Features and Soils

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7.1.7 Climate Change

Anthropogenic greenhouse gas (GHG) emissions since the pre-industrial era have resulted in increased atmospheric concentrations of carbon dioxide (CO_2), methane, and nitrous oxide (Intergovernmental Panel on Climate Change 2014). Climate change can have impacts on both natural and human systems, including, but not limited to, human health, adverse effects to agriculture and food security, increased storm severity, multi-decade droughts, and sea level rise. Increased frequency of severe storms is

anticipated to result in an increase in the extent and frequency of coastal flooding, loss of wetlands, erosion, increased flood risk, and increased salinity of rivers, bays, tidal estuaries, and groundwater, along with other land impacts throughout the world (Frumhoff et al. 2007).

7.1.8 Solid Waste and Hazardous Waste

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7.1.9 Cultural Resources

(b)(4)

7.1.10 Socioeconomics and Environmental Justice

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7.1.11 Public Health and Safety

Public health and safety, including, but not limited to, occupational health is a key component of manufacturing facility operations in the ENDS industry. Each facility has health and safety practices and procedures in place to protect facility workers and to prevent environmental releases that could result in exposures to the public.

7.2 Environmental Impacts

7.2.1 Regulatory Compliance

7.2.1.1 No Action Alternative

Under the No Action Alternative (no marketing order for the Proposed Action product), there would be no changes to regulatory compliance related to manufacturing, use, and disposal. The Applicant's suppliers provide comparable services (i.e., manufacture of finished e-liquids) to other companies, so their operations would be largely unchanged in the absence of the Proposed Action. Further, (b)(4) and (b)(4) facilities are both tolling/custom manufacturers, for whom contracting chemical product volumes at their facilities up to the maximum permitted quantities is in their own business interest, irrespective of the Applicant having their e-liquids manufactured at the facilities or not (no marketing order for the Proposed Action product). Potential capacity expansion of the facilities (b)(4) with the growing market for e-liquids might be a consideration for the future. Subject to unchanged nameplate capacity, under the No Action Alternative, there would be no changes to regulatory compliance from current conditions.

7.2.1.2 Proposed Action Alternative

7.2.1.2.1 Manufacturing the Products

Under the Proposed Action, there would be no anticipated impacts to regulatory compliance from manufacturing. Manufacturing facilities are in compliance with local, state, and federal environmental regulations. In addition, facilities have protection measures and practices in place to minimize or prevent the potential for lack of compliance.

7.2.1.2.2 Use of the Products

There would be no impacts to regulatory compliance related to use of the products under the Proposed Action. Product use by consumers occurs outside of the manufacturing facilities and, therefore, would not affect their compliance with local, state, and federal environmental regulations.

7.2.1.2.3 Disposal of the Products and Packaging

There would be no impacts to regulatory compliance related to disposal of the products under the Proposed Action. Manufacturers have disposal practices in place, mostly with third-party waste handlers and recyclers, to properly manage and remove waste from their facilities (see Section 7.1.1). A reasonable assumption is that the amount of used product and packaging material disposed in the municipal solid waste stream and from littering would not result in substantial accumulations of material that would impact the compliance of waste facilities, including recycling centers and solid waste landfills. Refer to the Confidential Appendix (Section D) for quantitative littering analysis of disposed product and packaging material.

7.2.2 Air Quality

7.2.2.1 No Action Alternative

Under the No Action Alternative, there would be no changes to air quality from current conditions, as other comparable products would be manufactured, used, and disposed of in the absence of the

Proposed Action. Further, (b)(4) facilities are both tolling/custom manufacturers, for whom contracting chemical product volumes at their facilities up to the maximum permitted quantities is in their own business interest, irrespective of the Applicant having their e-liquids manufactured at the facilities or not (no marketing order for the Proposed Action product). Potential capacity expansion of the facilities (b)(4) with the growing market for e-liquids might be a consideration for the future. Subject to unchanged nameplate capacity, under the No Action Alternative, there would be no changes to air quality from current conditions.

7.2.2.2 Proposed Action Alternative

7.2.2.2.1 Manufacturing the Products

Under the Proposed Action, there would be no changes to environmental air emissions from manufacturing. The manufacturing facilities may produce low concentrations of fugitive volatile organic compound (VOC) emissions; however, based on internal audits of local air district requirements by manufacturing facilities, the levels of emissions do not appear to reach regulated threshold values for VOCs and are therefore not likely to significantly change air quality.

7.2.2.2.2 Use of the Products

Under the Proposed Action, there would be no air quality impacts from product use. Localized air quality impacts related to public health are discussed in Section 7.2.11.2.2.

7.2.2.2.3 Disposal of the Products and Packaging

Under the Proposed Action, there would be no impacts to air quality from product disposal due to the lack of atmospheric emissions associated with disposal of the product and packaging. Emissions could be generated from municipal solid waste transport of disposed product and packaging (Section 7.2.7.2.3); however, the incremental contribution of those emissions would be negligible compared to the collective emissions associated with waste transport of disposed products and packaging from other ENDS industry companies. There will be no new or increased chemicals emitted from the disposal of the used product and packaging material (Confidential Appendix [Section D]).

7.2.3 Water Resources: Floodplains, Wetlands (and Waters of the U.S.), and Coastal Zones

7.2.3.1 No Action Alternative

Under the No Action Alternative, there would be no changes to water resources from current conditions, as other comparable products would be manufactured, used, and disposed of in the absence of the Proposed Action. Further, (b)(4) facilities are both tolling/custom manufacturers, for whom contracting chemical product volumes at their facilities up to the maximum permitted quantities is in their own business interest, irrespective of the Applicant having their e-liquids manufactured at the facilities or not (no marketing order for the Proposed Action product). Potential capacity expansion of the facilities (b)(4) with the growing market for e-liquids might be a consideration for the future. Subject to unchanged nameplate capacity, under the No Action Alternative, there would be no changes to water resources from current conditions

7.2.3.2 Proposed Action Alternative

7.2.3.2.1 Manufacturing of the Products

Under the Proposed Action, manufacturing would not lead to changes in water quality. According to the manufacturing facilities, there are no wastewater discharges from their facilities.

Under the Proposed Action, there would be no anticipated impacts to water resources. There are jurisdictional wetlands and waters in the vicinities of the (b)(4) facilities; however, e-

liquid manufacturing activities would not result in either temporary or permanent impacts. Potential facility expansions (b)(4) are not being considered in areas immediately adjacent to wetlands, floodplains, and coastal zones. Therefore, there would be no impacts to water resources from manufacturing under the Proposed Action.

Surface Water Releases

(b)(4)

Down-the-Drain Releases

(b)(4) modeling was also used to assess potential impacts from disposal of the selected ingredient down-the-drain through the municipal sewer and into the WWTP. The same selected chemicals were used for the surface water discharge scenario. The highest percentage of each ingredient in the product was used to determine the amount of each ingredient that would be released if containers of finished e-liquid were to break (Confidential Appendix [Section C]).

The (b)(4) modeling determined that there would be a very low likelihood of toxicity-related impacts from selected ingredients in the down-the-drain scenario (Confidential Appendix [Section B and D]).

7.2.3.2.2 Use of the Products

Under the Proposed Action, there would be no impacts to water resources related to product use. Exhaled vapor from consumers would not be expected to generate substantial volumes of harmful constituents that could deposit to waterbodies and result in decreased water quality or other impairments.

7.2.3.2.3 Disposal of the Products and Packaging

Under the Proposed Action, there would be no impacts to water resources related to product disposal. The Applicant's disposal instructions to consumers indicate that product should be recycled as electronic waste (e-waste) (Figure 3). The Applicant also recommends that users check local regulations or contact local household disposal services and/or recycling facilities for responsible disposal and recycling to reduce potential impacts to human health and the environment.

Consumers may also dispose of used products and packaging as litter rather than in the municipal solid waste stream. It is a reasonable assumption that the littered material would not accumulate in substantial amounts in localized areas. Rather, littered material would more than likely be dispersed in the environment, thus not representing point sources of pollution (Section 7.2.8). Under the Proposed Action, there would be no changes to the condition of water resources from disposal (Confidential Appendix [Section D]).

(b)(4)

7.2.4 Land Use and Zoning

7.2.4.1 No Action Alternative

Under the No Action Alternative, the manufacturing facilities would be less likely to expand operations in the absence of the Proposed Action. Therefore, no predictable changes to land use and zoning were identified. Further, (b)(4) facilities are both tolling/custom manufacturers, for whom contracting chemical product volumes at their facilities up to the maximum permitted quantities is in their own business interest, irrespective of the Applicant having their e-liquids manufactured at the facilities or not (no marketing order for the Proposed Action product). Potential capacity expansion of the facilities (b)(4) with the growing market for e-liquids might be a consideration for the future. Subject to unchanged nameplate capacity, under the No Action Alternative, there would be no changes to land use and zoning from current conditions.

7.2.4.2 Proposed Action Alternative

7.2.4.2.1 Manufacturing the Products

There could be changes to land use and zoning as a result of a potential expansion of the (b)(4) facility. There would be no impacts to land use and zoning under the Proposed Action, as county and local building and zoning codes would be adhered to during planning and construction of any proposed facility expansions. (b)(4) potential acquisition of a new, larger building would not result in land use changes, as the intention would be to identify a building with the same industrial land use and zoning.

7.2.4.2.2 Use of the Products

Under the Proposed Action, there would be no expected changes to land use and zoning related to product use.

7.2.4.2.3 Disposal of the Products and Packaging

Under the Proposed Action, there would be no changes to land use and zoning as a result of product disposal. Land use and zoning at the manufacturing facilities would not be directly impacted by product disposal. In addition, the amount of disposed product and packaging material would not be expected to accumulate in large enough volumes and mass to result in solid waste landfill expansions, new landfills, or recycling centers for waste disposal. Landfill capacity in the United States is considered sufficient for current domestic disposal practices, and projected disposed packaging waste (based on confidential marketing projections (Confidential Appendix [Section A]) would not result in impacts to the overall capacity of existing or planned waste handling resources (Confidential Appendix [Section D]). There would be no new or increased chemicals emitted from the disposal of the bottles and packaging material. Therefore, land use and zoning of landfills would not change as a direct result of disposal of the Proposed Action product.

7.2.5 Biological Resources

7.2.5.1 No Action Alternative

Under the No Action Alternative, there would be no changes to the condition of biological resources from current conditions, as other comparable products would be manufactured, used, and disposed of in the absence of the Proposed Action. Further, (b)(4) facilities are both tolling/custom manufacturers, for whom contracting chemical product volumes at their facilities up to the maximum permitted quantities is in their own business interest, irrespective of the Applicant having their e-liquids manufactured at the facilities or not (no marketing order for the Proposed Action product). Potential capacity expansion of the facilities (b)(4) with the growing market for e-liquids might be a consideration for the future. Subject to unchanged nameplate capacity, under the No Action Alternative, there would be no changes to biological resources from current conditions.

7.2.5.2 Proposed Action Alternative

7.2.5.2.1 Manufacturing the Products

No critical habitat for federally listed species is located within the manufacturing facilities' property boundaries. Manufacturing operations would not result in adverse effects to federally listed species found in areas around the facilities. Although potentially suitable habitat exists adjacent to the facilities, federally listed species are unlikely to occur within the facility property boundaries; therefore it is unlikely that any species potentially present in these adjacent areas would be negatively affected.

Modeling of chemicals from potential release scenarios indicated that EECs would be below chronic toxicity values for sensitive receptors (Section 7.2.3.2.1; Confidential Appendix [Section D]); thus, adverse effects due to chemical exposures would not be likely.

7.2.5.2.2 Use of the Products

Under the Proposed Action, there would not be any significant impacts to biological resources from product use. Exhaled vapor from product users would not be expected to generate substantial volumes of harmful constituents that could result in adverse impacts to ecological receptors from decreased air quality (for respiration) and water quality (ingestion or exposure).

7.2.5.2.3 Disposal of the Products and Packaging

Under the Proposed Action, it is assumed that used product and packaging would be properly recycled and/or disposed of in the municipal solid waste stream. The Applicant's disposal instructions to consumers indicate that the product should be recycled as e-waste (Figure 3). The Applicant also recommend that users check local regulations or contact local household disposal services and/or recycling facilities for responsible disposal and recycling to reduce potential impacts to human health and the environment.

Exposures of leached materials to biological resources could potentially occur due to improper disposal of used products as litter in the environment; however, it is not anticipated that disposed products and packaging would accumulate in sufficient quantities in single locations. Estimations of residual nicotine in littered products indicated that EECs in soil would be below ecotoxicity thresholds; therefore, impacts to biological resources would be highly unlikely (Section 7.2.6.2.3; Confidential Appendix [Section D]).

7.2.6 Geological Features and Soils

7.2.6.1 No Action Alternative

Under the No Action Alternative, there would be no changes to geological features and soils from current condition, as other comparable products would be manufactured, used, and disposed of in the absence of the Proposed Action. Further, (b)(4) facilities are both tolling/custom manufacturers, for whom contracting chemical product volumes at their facilities up to the maximum permitted quantities is in their own business interest, irrespective of the Applicant having their e-liquids manufactured at the facilities or not (no marketing order for the Proposed Action product). Potential capacity expansion of the facilities (b)(4) with the growing market for e-liquids might be a consideration for the future. Subject to unchanged nameplate capacity, under the No Action Alternative, there would be no changes to geological features and soils from current conditions.

7.2.6.2 Proposed Action Alternative

7.2.6.2.1 Manufacturing the Products

Under the Proposed Action, there would be no impacts to geological features and soils (terrestrial resources) from chemical releases during manufacturing operations. There could be minor and temporary impacts to soils from potential manufacturing facility expansions; however, the potential impacts directly

attributable to the Proposed Action would not be measurable, since both facilities produce finished e-liquids for companies other than the Applicant. Measures would be employed to minimize effects to native soils, including erosion and runoff control during pre-construction and construction activities related to facility expansions.

7.2.6.2.2 Use of the Products

Under the Proposed Action, there would not be significant impacts to geological resources and soils from product use. Exhaled vapor from product users would not be expected to generate substantial volumes of harmful constituents that could deposit to soil surface and cause adverse effects, such as contamination.

7.2.6.2.3 Disposal of the Products and Packaging

Under the Proposed Action, it is assumed that used products and packaging would be properly recycled and/or disposed of in the municipal solid waste stream. The Applicant's disposal instructions to consumers indicate that product should be recycled as e-waste (Figure 3). The Applicant also recommends that users check local regulations or contact local household disposal services and/or recycling facilities for responsible disposal and recycling to reduce potential impacts to human health and the environment. Consumers may also dispose of used products and packaging as litter rather than in the municipal solid waste stream. (b)(4) It is a reasonable assumption that littered material would not accumulate in substantial amounts in localized areas. Rather, it would more than likely be dispersed in the environment. Under the Proposed Action, there would be no changes to the condition of geological resources and soils from littering. (b)(4) (Section 7.2.8). Quantitative analyses were conducted to estimate EECs in the environment via U.S. Roadway and Urban Soil littering scenarios. The amount of disposed product and packaging were calculated based on confidential marketing projections. Derived EECs were then compared to ecotoxicity thresholds. The results indicated no exceedances of relevant ecotoxicity thresholds, and impacts to resources would be highly unlikely (Confidential Appendix [Section D]).

7.2.7 Climate Change

7.2.7.1 No Action Alternative

Under the No Action Alternative, there would be no changes to climate change from current conditions, as other comparable products would be manufactured, used, and disposed of in the absence of the Proposed Action. The No Action Alternative would not result in significant changes to existing manufacturing of comparable nicotine products. These products and other new products would continue to be manufactured even in the absence of the Proposed Action. Further, (b)(4) facilities are both tolling/custom manufacturers, for whom contracting chemical product volumes at their facilities up to the maximum permitted quantities is in their own business interest, irrespective of the Applicant having their e-liquids manufactured at the facilities or not (no marketing order for the Proposed Action product). Potential capacity expansion of the facilities (b)(4) with the growing market for e-liquids might be a consideration for the future. Subject to unchanged nameplate capacity, under the No Action Alternative, there would be no changes to climate change from current conditions.

7.2.7.2 Proposed Action Alternative

7.2.7.2.1 Manufacturing the Products

Under the Proposed Action, there could be impacts to climate change from manufacturing. For example, GHGs could be produced from product transport (shipping of raw materials and unfinished products [between manufacturing facilities] and finished products to retail shelves). However, the potential for

effects directly attributable to manufacturing of the Proposed Action product would likely be less than those associated with comparable ENDS products from other manufacturers.

7.2.7.2.2 Use of the Products

Under the Proposed Action, there would be no measurable impacts to climate change from product use. Exhaled vapor does not contain elevated concentrations of chemicals including VOCs that could impact climate change.

7.2.7.2.3 Disposal of the Products and Packaging

Under the Proposed Action, there would be no measurable impacts to climate change from product disposal. Spent product does not typically contain volumes of VOCs or other ingredients that can impact climate change. GHGs could be generated from municipal solid waste transport of disposed product and packaging; however, the incremental contribution of those emissions would be negligible compared to the collective emissions associated with waste transport of disposed products and packaging from other ENDS industry companies.

7.2.8 Solid Waste and Hazardous Waste

7.2.8.1 No Action Alternative

Under the No Action Alternative, there would be no changes to solid waste and hazardous waste from current conditions, as other comparable products would be manufactured, used, and disposed of in the absence of the Proposed Action. Further, (b)(4) facilities are both tolling/custom manufacturers, for whom contracting chemical product volumes at their facilities up to the maximum permitted quantities is in their own business interest, irrespective of the Applicant having their e-liquids manufactured at the facilities or not (no marketing order for the Proposed Action product). Potential capacity expansion of the facilities (b)(4) with the growing market for e-liquids might be a consideration for the future. Subject to unchanged nameplate capacity, under the No Action Alternative, there would be no changes to solid waste and hazardous waste from current conditions.

7.2.8.2 Proposed Action Alternative

7.2.8.2.1 Manufacturing the Products

Under the Proposed Action, manufacture of the product would likely increase total manufacturing waste from the facilities. However, the amount of waste directly attributable to the Proposed Action would be difficult to determine, since the facilities manufacture similar products for other companies. Therefore, it is not anticipated that manufacturing the new products would introduce significant amounts of hazardous waste. The waste that is generated at compliant manufacturing facilities is removed for disposal by third-party waste handlers, so it ends up in solid waste landfills, rather than accumulating in the environment.

7.2.8.2.2 Use of the Products

Under the Proposed Action, there would be no impacts to hazardous waste during product use. Exhaled vapor from product users would not be expected to generate substantial volumes of harmful constituents that could deposit and accumulate as hazardous waste in the environment.

7.2.8.2.3 Disposal of the Products and Packaging

The majority of ENDS products are not recyclable; however, it is assumed that product disposal specifications on packaging labels would be followed by consumers, so that the majority of spent product (containing only a minimal amount of residual ingredients) would enter the recycling stream or be disposed of in household solid waste, and ultimately in municipal solid waste landfills. A portion of used product and packaging could also be disposed of as litter in the environment. (b)(4)

(b)(4) The total mass of waste paper-based and plastic-based packaging material that may be disposed of into the natural environment has been estimated based in part on marketing projections (Confidential Appendix [Section A]) and is discussed further in the Confidential Appendix (Section D). (b)(4) and EECs were determined to be below relevant ecotoxicity thresholds (Section 7.2.6.2.3; Confidential Appendix [Section D]). (b)(4) Rather, it would more than likely be dispersed in the environment. Under the Proposed Action, there would be no changes to solid waste and hazardous waste from littering.

7.2.9 Cultural Resources

7.2.9.1 No Action Alternative

Under the No Action Alternative, there would be no changes to the current condition of cultural resources, as other comparable products would be manufactured, used, and disposed of in the absence of the Proposed Action. Further, (b)(4) facilities are both tolling/custom manufacturers, for whom contracting chemical product volumes at their facilities up to the maximum permitted quantities is in their own business interest, irrespective of the Applicant having their e-liquids manufactured at the facilities or not (no marketing order for the Proposed Action product). Potential capacity expansion of the facilities (b)(4) with the growing market for e-liquids might be a consideration for the future. Subject to unchanged nameplate capacity, under the No Action Alternative, there would be no changes to cultural resources from current conditions.

7.2.9.2 Proposed Action Alternative

7.2.9.2.1 Manufacturing the Products

Under the Proposed Action, there would be no anticipated impacts to historic properties or cultural resources, as a result of manufacturing activities. There is only one NRHP-listed resource in the vicinity of manufacturing operations, approximately 0.85 mile from the (b)(4) facility. Therefore, even in the event of a low-probability chemical release, impacts to cultural resources would be highly unlikely.

7.2.9.2.2 Use of the Products

Under the Proposed Action, there would be no impacts to historic properties or cultural resources from product use. Exhaled vapor from product users would not be expected to generate substantial volumes of harmful constituents that could deposit and accumulate on cultural resources.

7.2.9.2.3 Disposal of the Products and Packaging

Under the Proposed Action, there would be no impacts to historic properties or cultural resources from product disposal. It is assumed that used products and packing would end up in the municipal solid waste stream or as litter in the environment. It was determined that there would be a low likelihood of risk to soils from littering, therefore impacts to cultural resources would not be anticipated (Section 7.2.6.2.3; Confidential Appendix [Section D]).

7.2.10 Socioeconomics and Environmental Justice

7.2.10.1 No Action Alternative

Under the No Action Alternative, there would be no changes to socioeconomics from current conditions, because the amount of Proposed Action product does not represent a significant portion of the total

amount of ENDS products manufactured by the Applicant's suppliers. Further, (b)(4) facilities are both tolling/custom manufacturers, for whom contracting chemical product volumes at their facilities up to the maximum permitted quantities is in their own business interest, irrespective of the Applicant having their e-liquids manufactured at the facilities or not (no marketing order for the Proposed Action product). Potential capacity expansion of the facilities (b)(4) with the growing market for e-liquids might be a consideration for the future. Subject to unchanged nameplate capacity, under the No Action Alternative, there would be no changes to socioeconomics and environmental justice from current conditions.

No disproportionately high or adverse environmental justice impacts on minority or low-income populations is expected under the No Action Alternative.

7.2.10.2 Proposed Action Alternative

7.2.10.2.1 Manufacturing the Products

The Proposed Action would not cause any adverse socioeconomic impacts. The manufacturers are considering facility expansions or acquisitions of larger facilities (see Section 7.1) that could result in temporary jobs during construction, as well as hiring of permanent process engineers, chemists, and administrative staff. The creation of new jobs would result in positive socioeconomic benefits; such benefits would not be limited to the individual facilities, as increased production would result in new employment opportunities in other areas of the product life cycle. In addition, NJOY revenues from sale of these products could result in additional jobs at the company beyond vendor manufacturing facilities. New jobs, as well as local spending by NJOY staff could contribute to positive economic growth.

Because no significant impacts to environmental resources were identified, there would be no disproportionate impacts to environmental justice populations in the vicinity of the manufacturing facilities.

7.2.10.2.2 Use of the Products

Under the Proposed Action, no significant impacts to environmental resources from product use were identified; therefore, no disproportionate impacts would occur to environmental justice populations. In addition, the Proposed Action product is likely used by the same consumers who use other ENDS products on the market. Therefore, no disproportionate environmental justice impacts would be anticipated, since the ENDS products are essentially competing for the same market share.

7.2.10.2.3 Disposal of the Products and Packaging

Under the Proposed Action, no significant impacts to environmental resources from disposal were identified; therefore, no disproportionate impacts would occur to environmental justice populations.

7.2.11 Public Health and Safety

7.2.11.1 No Action Alternative

Under the No Action Alternative, there would be no changes to public health and safety from current conditions, as other comparable products would be manufactured, used, and disposed of in the absence of the Proposed Action. Further, (b)(4) facilities are both tolling/custom manufacturers, for whom contracting chemical product volumes at their facilities up to the maximum permitted quantities is in their own business interest, irrespective of the Applicant having their e-liquids manufactured at the facilities or not (no marketing order for the Proposed Action product). Potential capacity expansion of the facilities (b)(4) with the growing market for e-liquids might be a consideration for the future. Subject to unchanged nameplate capacity, under the No Action Alternative, there would be no changes to public health and safety from current conditions.

7.2.11.2 Proposed Action Alternative

7.2.11.2.1 Manufacturing the Products

Under the Proposed Action, adverse effects to public health and safety from manufacturing would not be expected. The manufacturing facilities are in compliance with local, state, and federal environmental regulations, which includes chemical exposure prevention measures, on-site health and safety protocols and trained staff, and in-house emergency response procedures and third-party responders. These controls would reduce the potential for exposures to workers and the public outside the facility property boundaries.

7.2.11.2.2 Use of the Products

(b)(4)

7.2.11.2.3 Disposal of the Products and Packaging

Under the Proposed Action, no significant environmental impacts were identified from used products and packaging disposal via littering (above); therefore, there would be no impacts to public health and safety related to product disposal.

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8 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 was 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).

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9 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; thus, no mitigation measures are required. Manufacturing facility BMPs including regulatory compliance measures and emergency response plans would be sufficient to prevent adverse impacts to environmental resources.

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10 List of Preparers

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11 Report Preparation and Review

The EA was prepared in accordance with 21 CFR 25.40.

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12 Agencies and Persons Consulted

No agencies or consultants were consulted during preparation of the EA.

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13 References

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