Environmental Assessment for Vuse Solo Power Unit

Prepared for:
United States Food and Drug Administration

Prepared by:
RAI Services Company

Date:
Oct 20, 2020

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1. APPLICANT AND MANUFACTURING INFORMATIONt

Applicant:

RAI Services Company[1] (RAIS) on behalf of R.J. Reynolds Vapor Company (RJRV)
401 N. Main Street
Winston-Salem, NC 27101

Manufacturer:

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2. EXECUTIVE SUMMARY

This environmental assessment has been prepared as required under 21 CFR 25.15 in accordance with 21 CFR 25.40, Food and Drug Administration's (FDA's or Agency's) regulation implementing the National Environmental Policy Act of 1969. The regulation, 21 CFR 25.15(a), states that "all applications or petitions requesting Agency action require the submission of an environmental assessment or a claim of categorical exclusion." RAI Services Company conducted the environmental assessment in accordance with 21 CFR 25.20 and 25.40 and relevant aspects of FDA technical guidance document(s), including the *Guidance for Industry: Environmental Assessment of Drug and Biologics Applications* (July 1998).[2]

This assessment was prepared by RAIS as part of the Premarket Tobacco Product Applications (PMTA) for the Vuse Solo family of products. The potential environmental impacts of the proposed action considering manufacturing, use, and disposal of the product are detailed below. The overall conclusion from the assessment is that there are no adverse environmental impacts identified for the Vuse Solo Power Unit.

[1] RAI Services Company ("RAIS") is a wholly owned subsidiary of Reynolds American Inc. ("RAI") that coordinates regulatory compliance for RAI's subsidiary companies. Throughout this application, we refer to "RAIS" or "the Company." For clarity and ease of review, all of the following subsidiaries of RAI are included within these terms: (1) RAI Services Company, the legal entity that prepared and filed the application on behalf of its affiliated subsidiaries, which is responsible for the scientific research supporting the application; (2) R.J. Reynolds Vapor Company, the PMTA applicant and the legal entity responsible for marketing products under the Vuse brand; and (3) R.J. Reynolds Tobacco Company, the legal entity responsible for providing analytical and other support services, which is registered under Section 905 as the importer of record of the Vuse Solo product.

[2] U.S. Food & Drug Administration. (1998). "Guidance for Industry: Environmental Assessment of Drug and Biologicse Applications." U.S. Department of Health and Human Services, Food & Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), July 1998, CMC6, Revision 1.

3. PRODUCT INFORMATION

3.1 Product Name and Variants

Vuse Solo is a closed format ENDS device sold as Power Unit components and pre-filled e-liquid cartridges. For this environmental assessment, only the Vuse Solo Power Unit is assessed. In use, the Power Unit is connected to a pre-filled e-liquid cartridge. Environmental assessments for the cartridge products in the Vuse Solo family, including thete-liquids contained in the cartridges, have been prepared separately. Table 1 lists the category and FDA-registered name for the product being assessed.

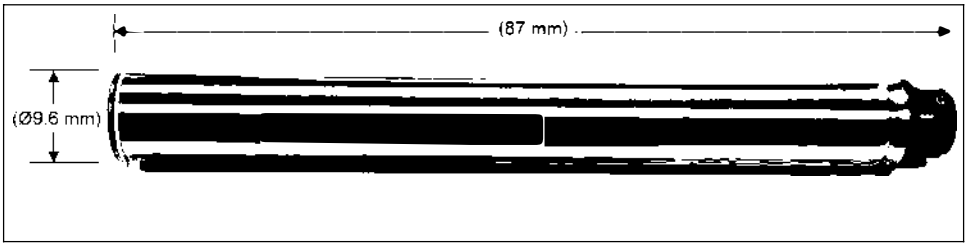
Table 1: Product Information

Registered Product Name	Vuse Solo Power Unit
Product Category	ENDS
Subcategory	ENDS Component
Product Packaging	Paperboard, cardboard
Package Quantity	1 Power Unit

3.2 Product Description

The Vuse Solo Power Unit is shown in Figure 1. The nominal length is 87 mm and the nominal diameter is 9.6 mm.

Figure 1: Vuse Solo Power Unit



The Vuse Solo Power Unit houses the electronics of the device and contains several essential elements: the lithium-ion battery, the controller, the puff sensor, and the LED. The lithium-ion battery is UL 1642 certified, non-removable, and can last for 6 months or more of regular use. The Power Unit parts are contained within a stainless steel outer tube.

3.3 Product Packaging Description

The Vuse Solo Power Unit is packaged with an accessory USB charger both seated in a molded pulp tray. The tray and an instruction insert are enclosed in a paperboard box that is labelled for sale to the consumer.

The retail packs of Power Units are further bundled in paperboard cartons and cardboard cases for shipping and distribution.

3.4 Product Composition

Components of the product and packaging are described by material type and unit of mass according to the standard International System of Units

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3.5 Actual and Projected Sales Volumes

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4. DESCRIPTION OF PROPOSED ACTION

4.1 Proposed Action

This environmental assessment is submitted as part of the PMTA for the Vuse Solo Power Unit. The proposed action is for FDA to issue a market authorization for the new product under section 910(c)(1)(A)(i) of the FD&C Act. [3]

4.2 Need for Action

RJRV markets Vuse Solo through interstate commerce in the United States (U.S.) and its territories and has submitted this environmental assessment as part of a PMTA to obtain a market authorization pursuant to Section 910(c)(1)(A)(i) of the FD&C Act.

4.3 Alternatives to the Proposed Action

The no-action alternative is for FDA to not issue a market authorization order for the Vuse Solo Power Unit. RAIS has not identified significant differences in environmental impacts between the proposed and alternative actions.

4.4 Location of Manufacturing

Vuse Solo Power Units and finished products are manufactured and packaged in (b) (4) by a contract manufacturer.

Table 2 lists the manufacturing site for the production of the Power Units and finished packaged products.

[3] U.S. Food & Drug Administration. (2009a). "Section 910 of the Federal Food, Drug, and Cosmetic Act – Application fore Review of Certain Tobacco Products." Availablefrom: https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/section-910-federal-food-drug-and-cosmetic-act-application-review-certain-tobacco-products

Table 2: Manufacturing Facility

Manufacturer	Facility Address	Latitude, Longitude	Part
(b)(4)			Power Units and Finished Products
	(b)(4)		

4.5 Location(s) of Use

The products will be distributed and sold for use across the United States and its territories.

4.6 Location of Disposal

Vuse Solo Power Units are reusable and rechargeable. These units can last 6 months or more and can be recycled rather than going to a waste stream, so disposal will occur infrequently. Power Units that are not recycled are likely to be disposed of as municipal solid waste (MSW). Packaging materials are likely to be disposed of as MSW. Packaging materials may also be recycled. It is possible that a very small percentage of the product could be improperly disposed of directly into the environment as litter corresponding with use patterns across the U.S.

5. POTENTIAL ENVIRONMENTAL IMPACTS FROM PRODUCT MANUFACTURING

5.1 Description of the Manufacturing Process(es)

Vuse Solo Power Units are assembled through manual processes from component parts at the manufacturer shown in Table 2. All of the manufacturing and packaging operations occur in (b)(4)

Following manufacturing, the finished product is imported to the U.S. and stored at a distribution center in North Carolina prior to commercial distribution.

5.2 Releases to the Environment From Manufacturing

Manufacturing of the Vuse Solo Power Unit does not result in the release of significant amounts of materials to the environment and does not consume significant amounts of natural resources. The components of the device do not contain new or unique compounds that would present different environmental impacts as compared to the production of other battery-powered electronic devices. Manufacturing of the product will not require additional resources (e.g., landfills, recycling centers) for disposal of manufacturing waste.

No additional environmental controls are needed due to manufacturing of the product.

No expansions of the manufacturing facilities are expected due to the manufacturing of the product.

5.3 Environmental Release / Disposal Regulations and Compliance Procedures

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5.4 Environmental Justice

The products are manufactured outside of the U.S., therefore there are no anticipated impacts to minority or low-income populations within the U.S.

5.5 Impacts of the No-Action Alternative

The environmental impact of the no-action alternative would not change the existing condition of manufacturing of tobacco products and would not differ from the proposed action.

6. POTENTIAL ENVIRONMENTAL IMPACTS FROM PRODUCT USE

6.1 Description of Product Use

Once the Vuse Solo Power Unit is connected to a cartridge, the product is activated by drawing air through the mouth-end of the cartridge. This puffing action and the resulting pressure differential activates the pressure sensor in the power unit. Activation of the pressure sensor signals the microcontroller in the power unit to send power to the heater in the cartridge. During the puff, the heater aerosolizes e-liquid within the cartridge which is then drawn through a hole in the mouth-end of the cartridge.

During charging, the Vuse Solo Power Unit is connected to the accessory USB charger which is in turn plugged into a standard USB port to provide electrical power to charge the battery in the Vuse Solo Power Unit.

As noted previously, environmental assessments for the Vuse Solo Cartridges, including the e-liquids within the cartridges, have been prepared separately.

6.2 Releases to the Environment From Product Use

As an electronic device, the Vuse Solo Power Unit generates no terrestrial, aquatic, or atmospheric releases during use or charging.

6.3 Environmental Justice

No emissions are expected due to use of the product, therefore, there would be no disproportionate impacts on minority, low-income, or other sensitive populations from product use.

6.4 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of use of cigarettes or other ENDS products.

7. POTENTIAL ENVIRONMENTAL IMPACTS FROM PRODUCT DISPOSAL

7.1 Assumptions Used in Calculating Environmental Fate

Upon purchase of the product, the consumer will remove the packaging material. Paper and paperboard components of the packaging can be recycled. The preferred method to dispose of paper and cardboard packaging is through a local recycling program. Most retail outlets will have a recycling program in place for disposal of shipping boxes. Municipal waste sites are acceptable disposal methods for packaging if local paper and paperboard recycling is not an option. It is anticipated that both the recyclable and non-recyclable packaging will, at times, be disposed of as solid waste. Therefore, the environmental loadings for this EA will be calculated as if all packaging material is disposed of as municipal solid waste (MSW). The potential for intentional or unintentional introduction directly into the environment is expected to be minimal for this product because the Power Unit is a reusable device and replaced infrequently.

The UL 1642 certified lithium-ion battery in the Power Unit is expected to last for 6 months or more, at which point the Power Unit will need to be replaced. Like many ENDS manufacturers, RJRV has provided ready access for consumers to information regarding disposal of the product. Text on the Vuse Solo packaging materials directs the consumer to visit www.vusevapor.com for important product information before use. On the website, under the Frequently Asked Questions (FAQs), the question of disposal of the Vuse product is addressed. A statement from that website directs the consumer to "Please dispose of Vuse cartridges, tanks, power units, and chargers responsibly. Your Vuse power unit contains a lithium-polymer battery, which should not be disposed of with regular household waste, crushed (e.g., trash compactor), or burned. Contact your local waste management officials for more information about disposing of batteries in accordance with state and local requirements." Once the Power Unit is ready to be disposed of, it is expected to be properly disposed of through e-waste recycling services or in MSW landfills. While the Power Units containing the lithium-ion battery and printed circuit boards are expected to be disposed of properly, it is possible that some may be discarded directly into the environment. This would result in only minor, localized exposure from materials in the Power Unit entering the environment. Therefore, this EA will conservatively evaluate the load placed on municipal solid waste as if all Power Units were disposed of as trash.

7.2 Equations Used to Calculate Loadings from Product Disposal

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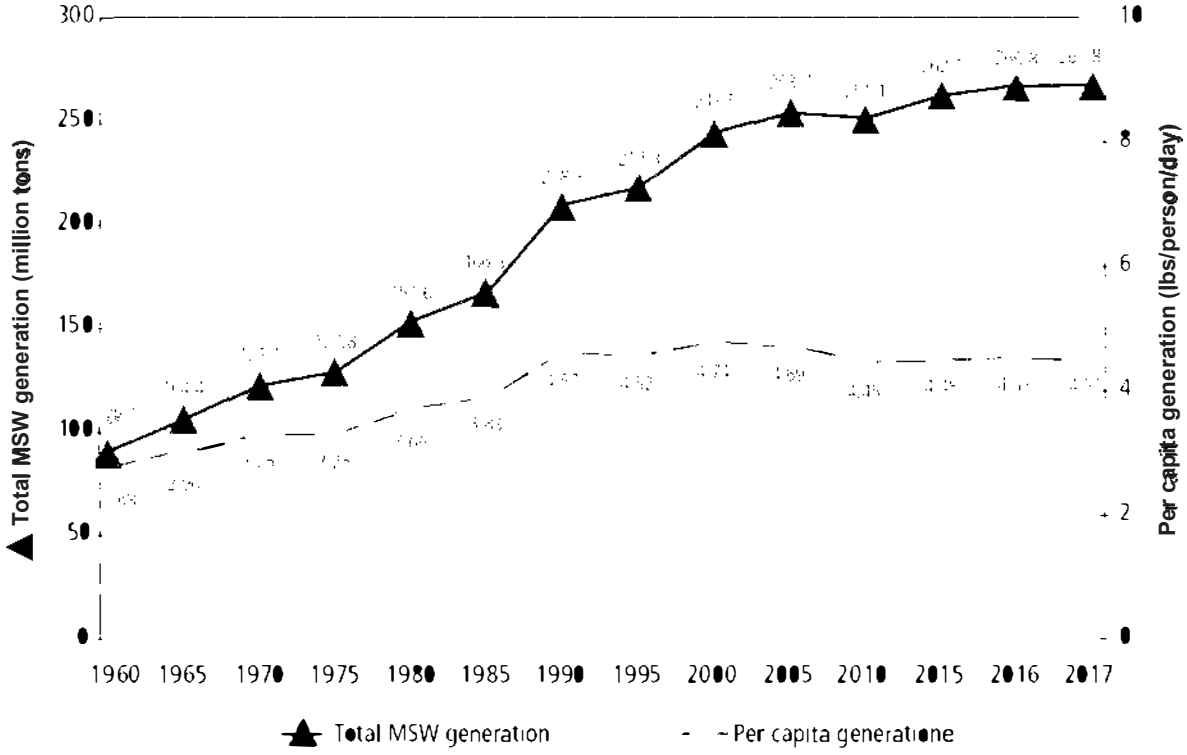
7.3 Contribution to Total Municipal Waste Load

Product waste must be examined in the context of the total MSW load in the United States. MSW is comprised of packaging, food waste, yard trimmings, furniture, electronics, tires, appliances, etc.

Waste generation in the United States has been increasing on an annual basis between 1960 and 2017 as shown in Figure 2.[4] In 2017, approximately 243 million metric tons of MSW was generated (values converted from short tons as originally reported). The annual increase has slowed but continues to rise.

Figure 2: MSW Generation Rates in the U.S.

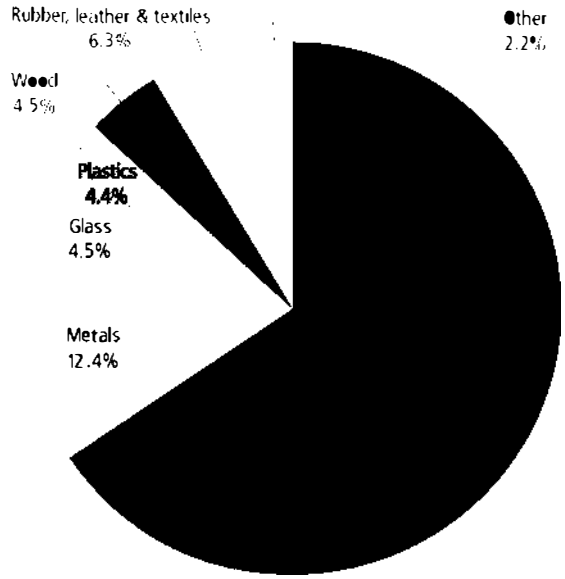


Of the 243 million metric tons of waste, approximately 61 million metric tons were recycled, 24 million metric tons were composted, 31 million metric tons were combusted with energy recovery, and 127 million metric tons were landfilled. According to Figure 3 below,[5] in 2017, paper and paperboard were most commonly recycled and accounted for 65.7% of overall recycled materials. Metals, glass, and plastics accounted for 12.4%, 4.5%, and 4.4% respectively. It can be assumed that the Vuse Solo packaging materials that are disposed of as MSW are similarly recycled.

[4] U.S. EPA. (2019). Advancing Sustainable Materials Management: 2017 Fact Sheet Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States. Available from: https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf

[5] Ibid.

Figure 3: MSW Recycling by Material in the U.S.



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of the new product is not expected to require additional resources for managing MSW.

7.3.1 Extended Analysis for Disposal of Lithium-ion Batteries

The lifespan of lithium-ion batteries, and therefore the Power Units which use them, varies based on frequency of use. The UL 1642 certified battery in the Vuse Solo Power Unit should last 6 months or more. Despite uncertainty in the length of time the lithium-ion batteries last before disposal, total annual disposal volumes are reasonably well estimated from the projected sales volumes for the Power Units.

Kang et al. measured leaching rates from lithium-ion batteries.[6] Their results suggested that according to federal regulations, some lithium-ion batteries would be classified as hazardous due to their lead (Pb) content. Newer lithium-ion batteries such as those used in the Vuse Solo Power Unit contain neither lead nor cadmium and therefore are considered universal waste rather than hazardous waste (https://www.epa.gov/hw/universal-waste). The battery used in Vuse Solo is a lithium-ion battery encased in a polymer pouch, sometimes referred to as lithium-polymer. The

[6] Kang, D. H., Chen, M., Ogunseitan, O. A. (2013). "Potential Environmental and Human Health Impacts of Rechargeable Lithium Batteries in Electronic Waste." *Environmental Science & Technology.* 47(10): 5495-503.

terms are used interchangeably in this document. If the battery case is broken, battery solvents may leach out and carry other soluble chemicals with them into the landfill.

By EPA regulation (40 C.F.R. Part 258), solid waste facilities built after October 9, 1993 must be equipped with composite liners and leachate collection systems to prevent leaching of waste into soil and water. Those built before October 9, 1993 are not required to retrofit with these liners but are required to monitor groundwater and take corrective action as needed. Therefore, unrestricted release of any potential lithium-ion battery leachate, and especially the small fraction potentially contributed byte-cigarette batteries, to the terrestrial or aquatic environment is unlikely.

For 2019, the annual global production of lithium-ion batteries was estimated at 160 GWh[7]. The specific energy of lithium-ion cells typically ranges from about 150 to 200 Wh/kg, giving a global production of at least 800,000 metric tons. Conservatively, assuming that the United States uses only 5% of global production this would result in an annual U.S. usage of 40 000 metric tons of lithium-ion batteries (b)(4)

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7.3.2 Extended Analysis for Electronic Waste Disposal

Ideally, the consumer would recycle the entire product. Conservatively, we assume that all of the electronic components are disposed of properly and then end up in municipal solid waste sites.

Duan *et al*. (2013) reported that of the 258.8 million units of used electronics generated in the U.S. in 2010[8], 171.4 million units were collected. On a weight basis, 1.5 million metric tons of used electronics were generated in the U.S. About 8.5% of the electronics collected were exported for recycling on a unit basis and about 3.1% on a weight basis. TVs and computer monitors dominated the waste on a weight basis, but mobile phones dominated on a unit basis.

In addition, the composition of the new product was reviewed to address any potential environmental release or exposure concerns. Based on this review, the electronic components are understood to meet requirements for the current Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS 2)[9] and Registration, Evaluation, Authorisation and Restriction of

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[7] Benchmark Mineral Intelligence. (Jan 19, 2019). *Who is Winning the Global Lithium Ion Battery Arms Race?*. Retrieved Nov 1, 2019 from https://www.benchmarkminerals.com/who-is-winning-the-global-lithium-ion-battery-arms-race/

[8] Duan, H., Miller, T. R., Gregory, J., Kirchain, R. (2013). "Quantitative Characterization of Domestic and Transboundarye Flows of Used Electronics Analysis of Generation, Collection, and Export in the United States." StEP (Solving the E-Waste Problem) December 2013.

[9] Restriction of Hazardous Substances in Electrical and Electronic Equipment, Directive 2011/65/EU. Available from: http://ec.europa.eu/environment/waste/rohs_eee/legis_en.htm

Chemicals (REACH)[10] regulations. No significant adverse effects resulting from environmental release or exposure are anticipated.

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7.4 Environmental Justice

There are no significant changes to socioeconomic conditions or environmental justice from the disposal of the product. Product and packaging waste would be recycled or disposed of in the same manner as waste from other tobacco products.

7.5 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of disposal of other competing tobacco products and associated packaging waste as these products would continue to be sold and used across the U.S.

8. MITIGATION MEASURES

Based upon the review of potential environmental impacts detailed above, RAIS concludes there are no adverse environment impacts for the Vuse Solo Power Unit. Therefore, no mitigation measures are discussed.

9. COMPLIANCE WITH ENVIRONMENTAL ACTS

No adverse effects on a species or the critical habitat of a species identified under the Endangered Species Act ("ESA") or the Convention on International Trade in Endangered Species of Wild Fauna and Flora ("CITES") are expected due to the proposed action. The locations of Vuse Solo manufacturing are not within or in close proximity to a habitat, critical or otherwise, of a threatened or endangered species per habitat maps made available by the U.S. Fish and Wildlife Service[11].

RAIS has completed a review of (a) endangered and threatened species listed by the U.S. Fish and Wildlife Service for both animals[12] and plants[13] and (b) the endangered and threatened species

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[10] Registration, Evaluation, Authorisation and Restriction of Chemicals, Regulation (EC) No 1907/2006. Available from: http://ec.europa.eu/environment/chemicals/reach/reach_en.htm

[11] U.S. Fish & Wildlife Services. Critical Habitat for Threatened & Endangered Species Maps. Available from: http://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77 Accessed and reviewed on November 15, 2019.

[12] U.S. Fish & Wildlife Services. ECOS Environmental Conservation Online System: http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcrithab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals Accessed on November 15, 2019.

listed in Appendices I, II, and III[14] of the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Based on that review, RAIS is not aware of any information to suggest that the manufacture and commercial distribution of Vuse Solo products would specifically jeopardize the existence of listed species or destroy or adversely modify any designated critical habitat for such species. To the best of our knowledge, none of the materials used in the manufacture of Vuse Solo products are listed by either the U.S. Fish and Wildlife Service or the CITES as sourced from endangered or threatened species.

Therefore, no adverse effects specific to a species or the critical habitat of a species identified under ESA and/or CITES associated with the manufacture and commercial distribution of the Vuse Solo products have been identified, and no adverse environmental effects associated with the proposed action are anticipated. We are also unaware of any information that suggests manufacture of the new product would result in the take, as that term is defined in the Endangered Species Act, 16 U.S.C. 1362, or 50 CFR 216.3, of an endangered or threatened species.

Further, RAIS is not aware of information to suggest that there are any extraordinary circumstances in these cases indicative of any adverse environmental impact as a result of the proposed action. Extraordinary circumstances include situations where: (1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; (2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements (40 CFR 1508.27(b)(10)); and (3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the ESA or the CITES to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law. To the best of our knowledge, no situations such as these apply to the manufacture of the product.

10. LIST OF PREPARERS

Paul H. Ayres, Ph.D., D.A.B.T (1986-2016)
Director, Scientific & Regulatory Affairs
RAI Services Company
Education: 1983. Ph.D. in Interdisciplinary Toxicology, University of Arkansas Medical Sciences
Experience: 35+ years in toxicology and tobacco science

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[13] U.S. Fish & Wildlife Services. ECOS Environmental Conservation Online System: http://ecos.fws.gov/tess_public/reports/ad-hoc-species-report?kingdom=P&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&fcrithab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&ffamily=on&header=Listed+Plants Accessed on November 15, 2019.

[14] Convention on International Trade in Endangered Species of Wild Fauna and Flora. https://cites.org/sites/default/files/eng/app/2019/E-Appendices-2019-11-26.pdf Listing valid from November 26, 2019 and accessed on December 5, 2019.

Lance Dooly, B.S.
Sr. Scientist, Scientific & Regulatory Affairs
RAI Services Company
Education: 1995. B.S. Physics, B.S. Chemistry, Georgia Institute of Technology
Experience: 20+ years in tobacco science and product development

11. LIST OF AGENCIES AND PERSONS CONSULTED

In accordance with 40 CFR 1508.9, this section includes a list of agencies and persons consulted in preparation of this environmental assessment. Feedback from FDA on prior submissions and examples of Environmental Assessments posted by FDA were considered in preparation of this assessment.

Agencies and Persons Consulted	Consultation
Endangered Species Act (ESA) (https://www.fws.gov/endangered/esa-library/pdf/ESAall.pdf)	Consulted endangered animal and plant species to confirm none of these materials are used to manufacture the new product
Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) (https://www.cites.org/)	Consulted the endangered and threatened species in Appendices I, II, and III to confirm none of these materials are used to manufacture the new product
National Environmental Policy Act (NEPA) (https://www.epa.gov/nepa)	Consulted on process and compliance with the Act
Max Hopkins, Sr. Staff Engineer Environment, Health & Safety (EHS) R.J. Reynolds Tobacco Company	Consulted on RAI environmental programs, and to confirm compliance, no Notices of Violation, and all applicable permits associated with federal, state, and local environmental regulations. EHS collaborates with the following external partners (b)(4) (b)(4)

12. CERTIFICATION

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

(b)(6)

(b)(6)

30-Oct-20 | 11:31 EDT

Michael W. Ogden, Ph.D.
Senior Vice President – Scientific & Regulatory Affairs

Date

(b)(4)

(b)(4)

Certificate Of Completion

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Winston-Salem, NC 27101
(b)(6) rjrt.com
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Signer Events	Signature	Timestamp
Michael W. Ogden (b)(6) @rjrt.com RAI Services Company Security Level: Email, Account Authentication (Required)	(b)(6) Signature Adoption: Pre-selected Style Signature ID: 145E0906-1AB6-417D-A484-8F18E86B8537 Using IP Address: (b)(6) With Signing Authentication via (b)(4) assword With Signing Reasons (on each tab): I approve this document	Sent: 10/30/2020 10:13:04 AM Viewed: 10/30/2020 11:31:08 AM Signed: 10/30/2020 11:31:42 AM

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In Person Signer Events	Signature	Timestamp
Editor Delivery Events	**Status**	**Timestamp**
Agent Delivery Events	**Status**	**Timestamp**
Intermediary Delivery Events	**Status**	**Timestamp**
Certified Delivery Events	**Status**	**Timestamp**
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Completed	Security Checked	10/30/2020 11:31:42 AM
Payment Events	**Status**	**Timestamps**

Electronic Record and Signature Disclosure

ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

From time to time, RAI Services (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through th (b)(4) system. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to this Electronic Record and Signature Disclosure (ERSD), please confirm your agreement by selecting the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the (b)(4) system.

Obtaining copies

You will have the ability to download and print documents we send to you through th (b)(4) system during and immediately after the signing session. You may access the documents for a limited period of time (usually 30 days) after the documents are first sent to you. **Note: All notices and disclosures will be sent to you electronically.**

In accordance with the procedures described herein, we will provide electronically to you through th (b)(4) system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To ensure you receive any notice or disclosure, we will provide all of the required notices and disclosures to the same email address that you have given us. You will receive all the disclosures and notices electronically. If you do not agree with this process, please let us know as described below in the To withdraw your consent with RAI Services section. Reference the To withdraw your consent with RAI Services section if you elect not to receive delivery of the notices and disclosures electronically from us.

How to contact RAI Services

You may contact us to let us know of your changes as to how we may contact you electronically and to withdraw your prior consent to receive notices and disclosures electronically as follows:

To contact us by email, send messages to: (b) (4) rjrt.com in the body of such request you must state your email, full name, mailing address, and telephone number.

To advise RAI Services of your new email address

To inform us of a change in your email address were we should send notices and disclosures electronically to you, you must send an email message to us at (b) (4) jrt.com and in the body of such request you must state: your previous email address, your new email address.

You (b)(4) account will allow for you to update it with your new email address through your account preferences.

To withdraw your consent with RAI Services

To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

i. Decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;

ii. Send us an email t(b)(6) @rjrt.com and in the body of such request you must state your email, full name, mailing address, and telephone number.

The consequences of your withdrawing consent to this ERSD will be that you may no longer have the ability to electronically sign documents with us.

Required hardware and software

The minimum system requirements for using the (b) (4) system may change over time. The current system requirements are found here (b) (4)

(b)(4)

Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to 'I a ree to use electronic records and signatures' before clicking 'CONTINUE' within th(b)(4) system.

By selecting the check-box next to 'I agree to use electronic records and signatures', you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
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U.S. FOOD & DRUG
ADMINISTRATION

FINDING OF NO SIGNIFICANT IMPACT

Marketing Orders for

Vuse Solo Power Unit, Vuse Replacement Cartridge Original 4.8% G1, and Vuse Replacement Cartridge Original 4.8% G2

Marketed by R.J. Reynolds Vapor Company

The Center for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental impact of these actions and has concluded that these actions will not have significant effects on the quality of the human environment. Therefore, environmental impact statements are not required.

R.J. Reynolds Vapor Company wishes to introduce one electronic nicotine delivery (END) component and two closed e-liquids into interstate commerce for commercial distribution in the United States and submitted to FDA premarket tobacco product applications to obtain marketing orders under the provisions of section 910 of the Federal Food, Drug, and Cosmetic Act.

FDA reviewed the applicant's environmental assessments (EA), dated October 20, 2020, for the three ENDS tobacco products in accordance with the Council on Environmental Quality's regulations (40 CFR 1500-1508) implementing the National Environmental Policy Act (NEPA) and FDA's NEPA regulations (21 CFR 25.40). The EAs concluded that the marketing orders would have no significant impact. The applicant's EAs are available to the public upon request.

The applicant's EAs evaluated potential environmental effects due to manufacturing, use, and disposal of the new products. No increased or new types of environmental impacts due to manufacturing the new products are anticipated. FDA does not foresee that use of the new products would result in new or different environmental impacts. FDA believes that the disposal of the new products is the same as the disposal conditions of other ENDS components and closed e-liquids that are currently marketed in the United States. Therefore, FDA does not foresee significant adverse impacts to the environment due to the proposed actions from manufacturing, use, and disposal of the new products.

Digitally signed by Luis G. Valerio -S
Date: 2021.10.08 09:54:25 -04'00'

Approved by

Luis G. Valerio, Jr., Ph.D., ATS
Associate Director
Division of Nonclinical Science
Office of Science
Center for Tobacco Products
U.S. Food and Drug Administration