

**Programmatic Environmental Assessment
for Marketing Orders for New Cigar Components
by New Image Global, Inc.**

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

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1. Applicant and Manufacturer Information

Applicant Name	New Image Global, Inc.
Applicant Address	15265 Alton Pkwy, Ste 120, Irvine, CA 92618
Manufacturer Name and Product Manufacturer Location	See Confidential Appendix 1

2. Product Information

Submission Tracking Numbers (STNs), New Products, and Predicate Products

New Product STN	New Product	Predicate Product
SE0018372	Royal Blunts XXL Sour Apple	Royal Blunts EZ Roll Sour Apple
SE0018374	Royal Blunts XXL Peach	Royal Blunts EZ Roll Georgia Peach
SE0018375	Royal Blunts XXL Blueberry	Royal Blunts EZ Roll Blueberry
SE0018376	Royal Blunts XXL Purple Haze	Royal Blunts EZ Roll Purple Haze
SE0018377	Royal Blunts XXL Wet Mango	Royal Blunts EZ Roll Wet Mango
SE0018378	Royal Blunts XXL Passion Fruit	Royal Blunts EZ Roll Passion Fruit
SE0018379	Royal Blunts XXL OGK	True Blunt EZ Roll Kush

Product Identification

Product Category	Cigars
Product Subcategory	Cigar Component
Product Number per Retail Unit	2
Product Package	Each cigar component is packaged in a polypropylene straw. Each straw is individually wrapped in biaxially-oriented polypropylene film, then packaged in a polyethylene terephthalate/aluminum pack or pouch retail unit containing 2 cigar components. 25 pouches are packaged in a paperboard display box. 50 display boxes are packaged in a corrugated board box.

3. Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the U.S. Food and Drug Administration (FDA) to issue marketing orders under provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act after finding the new products substantially equivalent to corresponding predicate products. The applicant wishes to introduce the new products into interstate commerce for commercial distribution in the United States and submitted to the Agency substantial equivalence (SE) reports to obtain marketing orders. The Agency shall issue the marketing orders if the new products are found substantially equivalent to corresponding predicate products. The applicant states that new and predicate products differ only in package quantity, from one cigar component (wrapper) in each predicate to two cigar components (wrappers) in each corresponding new product. New product packaging weights are greater than predicate product packaging weights, and new products include an additional packaging component: two biaxially-

oriented polypropylene film wraps per pouch (Confidential Appendix 2). The applicant states that new and predicate products are intended to be marketed simultaneously; new products will not replace corresponding predicate products (Confidential Appendix 3).

4. Alternative to the Proposed Actions

The no-action alternative is FDA does not issue marketing orders for the new products in the United States.

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

The new products are manufactured outside of the United States (Confidential Appendix 1). Compared with predicate products and other similar products, the applicant states that new product manufacture will involve the same or similar substances, will require no additional environmental controls or permits, and will generate the same types and volumes of air emissions, wastewater discharges, and other wastes.

6. Potential Environmental Impacts of the Proposed Actions and Alternative – New Product Use

The Agency evaluated potential impacts of new product use to resources in the environment and found no significant impacts based on Agency-gathered information and the applicant's submitted information. Included in the information that the Agency considered were projected first and fifth year market volumes (Confidential Appendix 3) and documented cigar use in the United States (Figure 1).

6.1 Affected Environment

The affected environment includes human and natural environments in the United States because marketing orders would allow the new products to be sold to consumers in the United States.

6.2 Air Quality

The impacts from use of combusted tobacco products include exposure to secondhand smoke (SHS) produced from burned cigars, cigarettes, cigarillos and pipes. Particles emitted by smoking may remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment to yield secondary pollutants, thirdhand smoke (THS). These pollutants coexist in a mixture in the environment alongside SHS (Burton, 2011; Matt et al., 2011).

There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

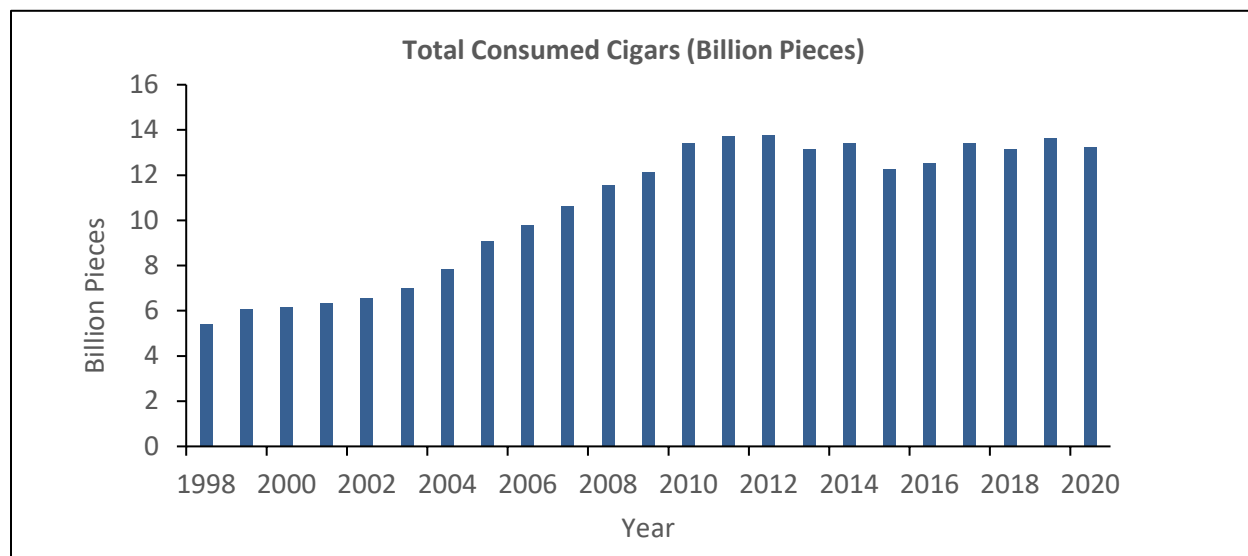
- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (U.S. Department of Health and Human Services, 2014).
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth. Such exposure can cause coughing, wheezing, phlegm, and breathlessness (U.S. Department of Health and Human Services, 2006a and 2006b).

- SHS causes more than 40,000 deaths a year (U.S. Department of Health and Human Services, 2014).

The consumption of cigars in the United States increased significantly from 1997 to 2011. Since 2011 through 2020, the trend of cigar use has stabilized with a minor decrease overall, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 1; U.S. Alcohol and Tobacco Tax and Trade Bureau, 2021). In combination with declines in use of other tobacco products, it is likely that this is responsible for the decline in SHS exposure observed in several studies that evaluated the levels of SHS exposure in children and nonsmokers living in homes of smokers (Homa et al., 2015; Yao et al., 2016).

Despite the considerable ethnic and racial disparities in SHS exposure in vulnerable populations, data from the National Health and Nutrition Examination Survey showed a decline in SHS exposure from 1999-2000 to 2011-2012 with the highest prevalence of exposure among non-Hispanic subpopulations (46.8%), compared to Mexican Americans (23.9%) and non-Hispanic whites (21.8%) in 2011-2012 (Homa et al., 2015). There were also significant declines in SHS exposure prevalence noted in 2000 and 2010 National Health Interview Survey Cancer Control Supplements. Exposure to SHS declined in Hispanics from 16.3% in 2000 to 3.1% in 2010, non-Hispanic Asians from 13.4% in 2000 to 3% in 2010, and non-Hispanic blacks from 31.2% in 2000 to 11.5% in 2010, as compared to exposures in non-Hispanic whites, which declined from 25.8% in 2000 to 9.7% in 2010 (Yao et al., 2016).

Figure 1. Use of Cigars in the United States, 1997 – 2020



As of December 2020, 28 states and the District of Columbia had implemented comprehensive smoke-free laws (American Lung Association, 2020). Such laws are also expected to reduce the levels of non-users' exposure to SHS and THS.

The Agency does not anticipate that new chemicals would be released into the environment as a result of use of the new products, relative to chemicals released into the environment due to use of similar products already on the market, because (1) combustion products from the new products would be released in the same manner as combustion products of other marketed cigar components, (2) the new

products are expected to compete with other currently marketed cigar components, and (3) ingredients in the new products are used in other currently marketed tobacco products.

6.3 Environmental Justice

Because new products are not expected to increase overall cigar or cigar component consumption, no new emissions are expected. Therefore, there would be no new disproportionate impacts on minority or low-income populations.

6.4 Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts from use of the new products under the proposed actions.

6.5 Impacts of the No-Action Alternative

The no-action alternative would not change the existing condition of use of cigars or cigar components, as similar tobacco products would continue to be marketed.

7. Potential Environmental Impacts of the Proposed Actions and Alternative – New Product Disposal

The Agency considered potential impacts of new product disposal to resources in the environment. Based on TTB data, which shows relatively stable cigar use rates in the United States since 2011 (Figure 1; U.S. Alcohol and Tobacco Tax and Trade Bureau, 2021), and the applicant's submitted information, including market volume projections for the new products (Confidential Appendix 3), the Agency found no significant impacts.

7.1 Affected Environment

The affected environment includes human and natural environments in the United States because marketing orders would allow the applicant to distribute and sell the new products to consumers in the United States.

7.2 Air Quality

The Agency does not anticipate that disposal of the new products or packaging materials would lead to the release of new or increased chemicals into the air.

No changes in air quality are anticipated from disposal of used or unused new products. Chemicals in the new products and any associated butt waste are commonly found in other currently marketed cigar components. Because the new products are anticipated to compete with other currently marketed cigar components, waste generated from used and unused new products would replace the same type of waste. Therefore, the fate and effects of materials emitted into the air from new product disposal are anticipated to be the same as for that of materials from disposal of other cigar components in the United States.

No changes in air quality from disposal of new product packaging materials would be expected because: (1) at least a portion of packaging waste is likely to enter the recycling stream, (2) packaging materials are commonly used in the United States, and (3) waste generated from packaging disposal (U.S. Environmental Protection Agency, 2020) is a minuscule portion of municipal solid waste per FDA's experience evaluating packaging waste generated from tobacco products.

7.3 Water Resources

No new impacts to water resources are expected from disposal of used or unused new products or packaging because chemicals in the new products and associated packaging would be the same or similar to those in currently marketed cigar components, and new products would compete with other currently marketed cigar components.

7.4 Biological Resources

The proposed actions are not expected to change the continued existence of any endangered species or result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. Endangered Species Act (ESA) because: (1) new product disposal would be similar to currently marketed similar products in the United States, and (2) there would be no anticipated increase in cigar component disposal because new products are anticipated to compete with similar products. The applicant states that the manufacturer indicates the manufacturing facility adheres to all guidelines established for species and habitat preservation around the facility. The applicant further indicates that they are not aware of circumstances associated with product manufacture or disposal that would adversely impact ESA or CITES (Convention on International Trade in Endangered Species of Wild Flora and Fauna) endangered or threatened species, or critical habitat.

7.5 Solid Waste

The Agency does not foresee that introduction of the new products would notably affect current waste generated from all cigar components. Waste generated from new product disposal would be handled in the same manner as waste generated from other cigar components in the United States. The number of cigar components would be equivalent to market projections (Confidential Appendix 3), and a portion of those would be littered.

7.6 Socioeconomics and Environmental Justice

The Agency does not anticipate changes in impacts to socioeconomic conditions or environmental justice from new product disposal. Wastes are expected to be handled in the same manner as wastes from other cigar components in the United States. No new emissions are expected and therefore there would be no new disproportionate impacts on minority or low-income populations.

7.7 Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts from disposal of the new products under the proposed actions.

7.8 Impacts of the No-Action Alternative

The no-action alternative would not change existing cigar component and cigar component packaging disposal in the United States because disposal of similar tobacco products would continue.

8. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this environmental assessment:

Preparers:

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Education: Ph.D. in Biological Sciences

Experience: Twenty-three years in environmental management and compliance

Expertise: Environmental toxicology, risk assessment, population management, regulatory compliance

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Gregory Gagliano, M.S., Center for Tobacco Products

Education: M.S. in Environmental Science

Experience: Thirty-nine years in environmental compliance and analysis

Expertise: Environmental toxicology, risk assessment, NEPA analysis, regulatory compliance

9. A Listing of Agencies and Persons Consulted

None.

10. References

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Confidential Appendix 1: Manufacturer Name and Product Manufacturer Location

Manufacturer Name	New Image Mexico S.A. de C.V.
Product Manufacturer Location	(b) (4)

Confidential Appendix 2: Comparison of New Products with Corresponding Predicate Products

STN	Product Quantity		Pouch ¹		Straw ²		Film Wrap ³		Display ⁴		Display ⁵	
	weight (g)											
	New	Predicate	New	Predicate	New	Predicate	New	Predicate	New	Predicate	New	Predicate
SE0018372												
SE0018374												
SE0018375												
SE0018376												
SE0018377												
SE0018378												
SE0018379												

¹ Polyethylene terephthalate/aluminum pack or pouch containing 2 cigar components

² 2 polypropylene straws per pouch

³ Each straw is individually wrapped in biaxially-oriented polypropylene film.

⁴ 25 pouches are packaged in a paperboard display box.

⁵ 50 display boxes are packaged in a corrugated board box.

Confidential Appendix 3: Projected Market Volumes and Percent of United States Cigar Use Attributed to the New and Predicate Products

First- and fifth-year market volume projections for the new and predicate products, in lieu of unavailable cigar component data, were compared with total forecasted cigar use in the United States.¹ New and predicate products would account for about 0.3145% and 0.3972% of forecasted United States cigar use in the first and fifth years of marketing, respectively.

STN	Number of Units ²						
	Current	First Year			Fifth Year		
	Predicate Product	New Product	Predicate Product	% of Total Cigars Used ³	New Product	Predicate Product	% of Total Cigars Used ⁴
SE0018372	(b) (4)						
SE0018374							
SE0018375							
SE0018376							
SE0018377							
SE0018378							
SE0018379							
Total							
STN	Unit Weight (mg)		Metric Tons				
	New Product	Predicate Product	Current	First Year		Fifth Year	
			Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0018372	(b) (4)						
SE0018374							
SE0018375							
SE0018376							
SE0018377							
SE0018378							
SE0018379							
Total							

¹ The Agency used historical data about total cigar use from 1997 to 2020 (U.S. Alcohol and Tobacco Tax and Trade Bureau, 2021) to mathematically estimate the total number of cigars used in the United States. Using the best-fit trend line with an R² value of 0.9287, the forecasted number of cigars used in the United States is estimated at 13.42 billion cigars in the first year and 12.75 billion cigars in the fifth year of marketing the new products.

² Unit = 1 cigar component

³ Projected Market Occupation of the New and Predicate Products in the United States (%) = $\frac{\text{Projected Market Volume of the New and Predicate Products (\# of cigar components)}}{\text{Projected Use of Cigars in United States (\# of cigars)}} \times 100$

⁴ Ibid.