



August 25, 2017

**SUBSTANTIALLY EQUIVALENT**

Japan Tobacco International USA Inc.  
Attention: Paisley Cameron, Director, Scientific & Regulatory Affairs  
500 Frank West Burr Boulevard, Suite 24  
Teaneck, NJ 07666

**FDA Submission Tracking Number (STN): SE0013536**

Dear Ms. Cameron:

The Food and Drug Administration (FDA) completed review of your Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce (SE Report), submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), for the following tobacco product:

**New Tobacco Product**

<b>Tobacco Product Manufacturer:</b>	Japan Tobacco International, U.S.A., Inc.
<b>Tobacco Product Name<sup>1</sup>:</b>	Wave Menthol King Size
<b>Tobacco Product Category:</b>	Cigarette
<b>Tobacco Product Sub-Category:</b>	Combusted, Filtered
<b>Package Type:</b>	Hard Pack
<b>Package Quantity:</b>	20 cigarettes
<b>Length:</b>	84 mm
<b>Diameter<sup>2</sup>:</b>	7.9 mm
<b>Ventilation:</b>	(b) (4)
<b>Characterizing Flavor:</b>	Menthol
<b>Additional Property:</b>	Monogrammed tipping paper

<sup>1</sup> Brand/sub-brand or other commercial name used in commercial distribution

<sup>2</sup> The applicant submitted the circumference which allowed for a calculation for diameter

Based on our review of your SE Report, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and substantially equivalent to the following tobacco product, which was commercially marketed in the United States as of February 15, 2007:

**Predicate Tobacco Product**

<b>Tobacco Product Manufacturer:</b>	Japan Tobacco International, U.S.A., Inc.
<b>Tobacco Product Name<sup>3</sup>:</b>	Wave Menthol King Size
<b>Tobacco Product Category:</b>	Cigarette
<b>Tobacco Product Sub-Category:</b>	Combusted, Filtered
<b>Package Type:</b>	Hard Pack
<b>Package Quantity:</b>	20 cigarettes
<b>Length:</b>	84 mm
<b>Diameter<sup>4</sup>:</b>	7.9 mm
<b>Ventilation:</b>	(b) (4)
<b>Characterizing Flavor:</b>	Menthol
<b>Additional Property:</b>	Monogrammed cigarette paper

Under the provisions of section 910 and 905(j) of the FD&C Act, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above.

To fulfill the provisions of section 910(a)(4) of the FD&C Act, you submitted a summary of any health information related to the tobacco product in your SE Report and provided a statement that any such information will be available upon request by any person. No later than 30 days from the date of this letter, we will make your summary available to the public.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

It is important to note our finding of substantial equivalence for your new tobacco product specified above to an appropriate predicate tobacco product permits marketing of your new tobacco product. Our finding does not mean FDA “approved” the new tobacco product specified above; therefore, you may not promote or in any way represent the new tobacco product specified above, or its labeling, as being “approved” by FDA. See Section 301(tt) of the FD&C Act.

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<sup>3</sup> Brand/sub-brand or other commercial name used in commercial distribution

<sup>4</sup> The applicant submitted the circumference which allowed for a calculation for diameter

The finding that your product is substantially equivalent to the predicate product is based upon the information you provided in your SE Report and the standards contained in the FD&C Act, Section 910(a)(3). This marketing order is subject to reconsideration, with notice to the manufacturer, and rescission to the extent authorized by law.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also labeling and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements, including those which may be forthcoming. FDA will monitor your compliance with these applicable statutes and regulations.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at <http://www.fda.gov/TobaccoProducts>. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov), or [SmallBiz.Tobacco@fda.hhs.gov](mailto:SmallBiz.Tobacco@fda.hhs.gov).

We encourage you to submit all regulatory correspondence electronically via the CTP Portal (<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm>)<sup>5</sup> using eSubmitter (<http://www.fda.gov/ForIndustry/FDAeSubmitter>). Alternatively, submissions may be mailed to:

Food and Drug Administration  
Center for Tobacco Products  
Document Control Center (DCC)  
Building 71, Room G335  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

The CTP Portal and FDA Electronic Submission Gateway (ESG) are both generally available 24 hours a day, seven days a week. Submissions delivered to DCC by couriers or physical mail will be considered timely if received during delivery hours on or before the due date (see <http://www.fda.gov/tobaccoproducts/aboutctp/contactus/default.htm>); if the due date falls on a weekend or holiday the delivery must be received on the prior business day. We are unable to accept regulatory submissions by e-mail.

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<sup>5</sup> The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal

If you have any questions, please contact Sarah Vichensont, Regulatory Health Project Manager, at (240) 402-6104.

Sincerely,

Digitally signed by Matthew R. Holman -S

Date: 2017.08.25 12:38:34 -04'00'

Matthew R. Holman, Ph.D.

Director, Office of Science

Center for Tobacco Products