U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

July 05, 2018

**NOT SUBSTANTIALLY EQUIVALENT**

Heritage Tobacco LLC
ATTENTION: Luis Figueredo, Attorney
Figueredo Law LLC
8455 SW 155th Street
Palmetto Bay, FL 33157-2180

**FDA Submission Tracking Number (STN):** SE0003206

Dear Mr. Figueredo:

We have completed our 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 (FD&C Act), for the following tobacco product:

**New Tobacco Product**

| | |
|---|---|
| **Date of Submission:** | March 21, 2011 |
| **Date of Receipt:** | March 22, 2011 |
| **Product Manufacturer:** | Heritage Tobacco LLC |
| **Product Name:**[1] | Union Platinum King Box |
| **Product Category:** | Cigarettes |
| **Product Sub-Category:** | Combusted, Filtered |
| **Package Type:** | Box |
| **Package Quantity:** | 20 Cigarettes |
| **Characterizing Flavor:** | None |
| **Length:** | 84 mm |
| **Diameter:**[2] | 7.8 mm |
| **Ventilation:** | 39.2 % |

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The applicant submitted the circumference which allowed for a calculation of diameter.

We have determined that your SE Report does not establish that the new tobacco product specified above is substantially equivalent to the following predicate tobacco product:

**Predicate Tobacco Product**

| | |
|---|---|
| **Product Manufacturer:** | Heritage Tobacco LLC |
| **Product Name:**[1] | Union Gold King Box |
| **Product Category:** | Cigarettes |
| **Product Sub-Category:** | Combusted, Filtered |
| **Package Type:** | Box |
| **Package Quantity:** | 20 Cigarettes |
| **Characterizing Flavor:** | None |
| **Length:** | 84 mm |
| **Diameter:**[2] | 7.8 mm |
| **Ventilation:** | 39.2 % |

We acknowledge receipt of your July 24, 2017, amendment, which was considered for this decision.

We have described below our basis for this determination.

1. Your SE Report contains limited information and does not include sufficient detail to identify differences between the new and predicate tobacco products. You state that there are no differences in the ingredients, materials, heating source, composition and other features, yet, in your July 2016 amendment, you provide evidence that several components changed:

    a. The adhesives changed from (b) (4) [redacted] on 10/25/2007
    b. The tobacco blend changed from (b) (4) [redacted] on 6/18/2010
    c. The cigarette paper changed from non-FSC to FSC between 3/14/2008 and 3/31/2011

    You are responsible for all information pertaining to the products in these SE Reports.

    Component changes in a cigarette can include changes in the ingredients and may potentially affect the smoke chemistry. A detailed list is needed clearly stating all of the component and ingredient differences between the new and predicate tobacco products. If there are differences between the components of the new and predicate tobacco product, scientific evidence and a rationale are needed as to why the differences do not cause the new tobacco product to raise different questions of public health.

2. Your SE Report contains limited tobacco blend information and does not include sufficient detail to fully characterize the tobacco blend composition of the new and predicate tobacco product. For example, on page 90 of the July 2016 amendment, you provide a breakdown of a tobacco blend but do not identify to which product this blend pertains. Furthermore, the values for this tobacco blend are provided in relative quantities (i.e., percent) without providing the units for the numerator and denominator. Additionally, on page 90, you state that: “This blend contains casings and flavorings.” However, you provide the mass of only the tobaccos in the blend of one cigarette (i.e., mg/cig) without ingredients added to the tobacco.

    We need any other information you may have that uniquely identifies the tobacco used in the new and predicate tobacco products. This is the information that you rely on to ensure that the tobacco used in the new and predicate tobacco products is identical for both products. For example, if you

use a tobacco grading system, it would be helpful to know the tobacco grade (along with an explanation of the grading system) for each type of tobacco used in the new and predicate tobacco products. Additionally, your SE Report lists (b) (4) as a type of tobacco in your tobacco blend. However, you do not identify the tobacco or other ingredients in the (b) (4). It is important to know what ingredients, specifically, are included in the different (b) (4) in order to ensure that changes in (b) (4) do not raise different questions of public health. Information is needed on ingredient composition of the (b) (4) and *all* of the following for the new and predicate tobacco products:

a. All tobacco types used to manufacture the products
b. Quantities of all tobacco types expressed as mass per cigarette
c. Information to uniquely identify all tobacco (e.g., tobacco grading system)

Tobacco blend changes between the new and predicate tobacco products may potentially affect the smoke chemistry by affecting the HPHC yields. If there are any differences in tobacco blends between the new and predicate tobacco products, a rationale for each difference with evidence and a scientific discussion is needed for why the difference does not cause the new product to raise different questions of public health.

3. Your SE Report provides information about ingredients added to the new and predicate tobacco products. The information provided for ingredients does not include sufficient detail to fully characterize the composition of the new and predicate tobacco products. For example, your SE Report does not clearly list ingredients in all components of the new and predicate tobacco products. Furthermore, you state that the cigarette paper changed from non-FSC to FSC paper. However, the cigarette paper ingredient differences between the new and predicate tobacco products were not provided. Ingredient quantities are provided as percentages, grams, kg/g, ppm, and ranges of percentages, but you do not specify the original units of the numerator and denominator, define the denominator, or the cigarette mass. Therefore, ingredient quantities cannot be compared.

   There appears to be many errors in the submitted ingredient listings. Most notably, quantities appear to be placed in the incorrect row with the ingredient tables. Furthermore, you provided two different sets of ingredient data labeled “predicate product” and “grandfathered product” in addition to the “new product” data without clear indication as to which sets of data should be evaluated. Without complete, accurate, and clear ingredient information, we cannot determine whether the new and predicate product are substantially equivalent. A detailed side-by-side comparison of the new and predicate tobacco products is needed in a table organized by product and component including the following information:

   a. All ingredients used to manufacture the products, including individual ingredients in complex ingredients
   b. Quantities of all ingredients expressed as mass per cigarette (i.e., mg/cigarette)
   c. Information to uniquely identify each ingredient (e.g., CAS #, grade/purity, and function)

   If there are any differences in composition between the new and predicate tobacco products, scientific evidence and a rationale are needed for why each difference does not cause the new tobacco product to raise different questions of public health.

4. Your SE Report lacks HPHC mainstream smoke data for the predicate tobacco product. You did provide ammonia, three aromatic amines, benzo[a]pyrene, carbon monoxide, four carbonyls,

nicotine, NNN, NNK, and five volatiles yields under both the ISO and CI smoking conditions for the new product, but you did not provide these HPHC yields for the predicate tobacco product. As such, FDA is unable to determine the differences in characteristics between the new and predicate tobacco products. For example, you state that the cigarette paper changed from non-FSC to FSC, and the combustion of sodium alginate (a component of banded FSC paper) may result in the formation of acetaldehyde and benzene. Additionally, acetaldehyde, formaldehyde, and benzene are potential pyrolysis products from cellulose, which is contained in flax fiber and wood pulp fiber (other components of banded FSC paper). You provided these HPHCs for the new tobacco product, however these HPHCs are also needed for the predicate tobacco product in order for FDA to compare any HPHC differences between the new and predicate tobacco products.

These HPHC measurements would help determine whether significant changes cause the new tobacco product to raise different questions of public health. The measurement of HPHC quantities under both ISO and Canadian Intense smoking regimens would best characterize the delivery of constituents from these products. FDA recommends that appropriate measures be taken to minimize data variability and systematic bias. Such measures include, but are not limited to, using the same laboratory, the same type of smoking machine, the same methods, similar sample storage conditions and duration, and testing within similar timeframe. The following information about HPHC testing is also needed so that we can fully evaluate the differences in HPHC quantities between the new and predicate products:

a. Reference product datasets (e.g., 1R6F)
b. Quantitative test protocols and method used
c. Testing laboratory and their accreditation(s)
d. Length of time between date(s) of manufacture and date(s) of testing.
e. Number of replicates
f. Standard deviation(s)
g. Complete data sets
h. A summary of the results for all testing performed
i. Storage conditions prior to initiating testing

If your test methods are national or international test standards, you need to identify the standard(s) and any deviation(s) from those standards.

It is an applicant's responsibility to provide appropriate scientific evidence and data for the predicate tobacco product. If your predicate tobacco product is not available for testing, there are options which you may choose to try to demonstrate substantial equivalence. Below are some options, though alternative options may be acceptable. For example, the predicate tobacco product could be manufactured at present day consistent with the product composition and design specifications in place at the time the grandfathered predicate product was originally manufactured. In this case, the mainstream smoke HPHC data should be accompanied by documentation demonstrating that the manufacture of the predicate tobacco product at present day is reflective of the predicate tobacco product at the time of original manufacture. Another option would be to submit mainstream smoke HPHC data for products other than the new and predicate tobacco product (referred to as surrogate tobacco products) that could be extrapolated to the new and predicate tobacco product. In this case, data for the surrogate tobacco products could be submitted in place of data for the new and predicate tobacco product; the data should demonstrate that the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health. In order to extrapolate such data, the HPHC smoke data should be produced from surrogate tobacco products as similar as possible in

characteristics to the new and predicate tobacco product, and enough information should be provided to demonstrate that these comparisons are valid. In addition to the smoke data, information comparing the surrogate tobacco products to the new and predicate tobacco product should also be submitted.

5. Your SE Report provides some information on the design parameters for the new and predicate tobacco products. However, your SE Report does not include all of the design parameters necessary to fully characterize the new and predicate tobacco products. In order to adequately characterize the products, it is necessary to compare key design parameters. Target specifications and upper and lower range limits are needed for *all* of the following cigarette design parameters for the new and predicate tobacco products unless otherwise specified:

    a. Cigarette draw resistance (mm $H_2O$) (predicate product only)
    b. Tobacco filler mass (mg) (predicate product only)
    c. Tobacco rod density (g/$cm^3$) (predicate product only)
    d. Tobacco oven volatiles (OV) (%) (predicate product only)
    e. Tipping paper length (mm) (predicate product only)
    f. Cigarette paper base paper basis weight (g/$m^2$) (predicate product only)
    g. Cigarette paper base paper porosity (CU) (predicate product only)
    h. Cigarette paper band porosity (CU) (predicate product only)
    i. Cigarette paper band width (mm) (predicate product only)
    j. Cigarette paper band space (mm) (predicate product only)
    k. Filter efficiency (%) (predicate product only)
       [If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)]
    l. Filter length (mm) (predicate product only)
    m. Filter pressure drop (mm $H_2O$)

    Additionally, the upper and lower range limits are needed for *all* of the following cigarette design parameters for the new and predicate tobacco products:

    n. Cigarette length (mm) (predicate product only)
    o. Cigarette circumference (mm) (predicate product only)
    p. Filter ventilation (%) (predicate product only)

    For each of the above parameters, provide the necessary data on a per unit of product basis (e.g., tipping paper length should be reported in mm per cigarette). If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), you need to state as such and provide a scientific rationale.

    If a difference exists between the new and predicate tobacco product, a rationale is needed for each difference in the target specification and range limits with evidence and a scientific discussion for why the difference does not cause the new tobacco product to raise different questions of public health.

    Note that filter density, denier per filament, and total denier are necessary because filter efficiency (%) was not provided. As an alternative to submitting the information described above for filter density, denier per filament, and total denier, you may have provided target specification and upper and lower range limits for filter efficiency.

6. Your SE Report includes design parameter specifications but does not include data confirming that specifications are met. Test data (i.e., measured values of design parameters), including **test protocols, quantitative acceptance criteria, data sets, and a summary of the results** are needed for *all* of the following cigarette design parameters for the new and predicate tobacco products:

    a. Puff count
    b. Cigarette draw resistance (mm $H_2O$)
    c. Tobacco filler mass (mg)
    d. Tobacco oven volatiles (OV) (%)
    e. Filter ventilation (%)
    f. Cigarette paper base paper basis weight ($g/m^2$)
    g. Cigarette paper base paper porosity (CU)
    h. Cigarette paper band porosity (CU)
    i. Filter efficiency (%) [If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)]
    j. Filter pressure drop (mm $H_2O$)

    For each of the above parameters, the necessary data should be provided on a per unit of product basis (e.g., filter pressure drop should be reported in mm per cigarette). If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), you needed to state as such and provide a scientific rationale.

    Certificates of analysis from the material supplier may have satisfied this concern. If you choose to address this concern by providing certificates of analysis for any of the parameters listed above, the certificates of analysis must include: target specification; quantitative acceptance criteria; parameter units; test data average value; and either the standard deviation of the test data or the minimum and maximum values of the test data. The certificate of analysis must be a complete, unaltered certificate of analysis from the material supplier.

    Additionally, for the design parameters listed above that were tested according to national or international standards you needed to identify the standards and state what deviations, if any, from the standards occurred.

    If you choose to provide filter efficiency in place of filter density, denier per filament, and total denier, you should have provided test data as described above for filter efficiency.

7. Your SE Report indicates that the new and predicate tobacco products may use multiple materials including cigarette base paper, tipping paper, filter tow, and plug wrap materials. You state that you do not use multiple combinations of these materials, however you list multiple suppliers for cigarette base paper and in the listing of materials you provide multiple labels for each cigarette paper, tipping paper, filter tow, and plug wrap material. For example, cigarette base paper is named several times, sometimes as "(b) (4) [redacted]" and sometimes as "(b) (4) [redacted]," indicating there may be two different cigarette base papers with different porosities used in one product.

    In accordance with section 910(a)(1)(B) of the FD&C Act, each tobacco product modification, including use of an alternate material, constitutes a new tobacco product. Each identified new and predicate tobacco product must consist of a single combination of cigarette paper, tipping paper,

filter tow, and plug wrap materials. You should either reorganize your listing of materials to clarify the use of multiple materials or identify the following:

a. Every unique material combination in the predicate tobacco product that was on the market as of February 15, 2007.
b. Every unique material combination in the new tobacco product that was on the market between February 15, 2007 and March 22, 2011. Each specific combination of materials will be considered a single new tobacco product and evaluated individually in accordance with Section 910(a)(2)(B) of the FD&C Act.

For each identified new and predicate product, based on each combination of cigarette paper, tipping paper, filter tow, and plug wrap materials, you needed to provide data generated from testing of design parameters and HPHCs. You state that you no longer manufacture the predicate tobacco product and, therefore, are unable to provide the necessary design parameter data. Even if you no longer manufacture the predicate product, you still need to fully characterize the new and predicate tobacco product and, if the characteristics are different, you needed to demonstrate that the new tobacco product does not raise different questions of public health. Some potential options for obtaining data on the predicate tobacco product include, but are not limited to:

- Manufacture the predicate tobacco product at present day, consistent with the product composition and design specifications in place at the time the predicate tobacco product was originally manufactured. In this case, design parameter data should be accompanied by documentation demonstrating that the manufacture of the predicate tobacco product at present day is reflective of the predicate tobacco product at the time of original manufacture.
- Submit design parameter data for a tobacco product other than the predicate tobacco product (referred to as a surrogate tobacco product) that can be extrapolated to the predicate products. In this case, data for the surrogate tobacco product could be submitted in place of data for the predicate tobacco product. Information and data would need to be provided to demonstrate that data for the surrogate tobacco product can be extrapolated to the predicate tobacco product. For example, the design parameters specifications for the predicate and surrogate tobacco products should be compared and an explanation provided for how each difference in specification would affect the extrapolation from the surrogate to predicate products. Additionally, if a difference exists between the new and predicate product identified for each SE Report, scientific evidence and a rationale are needed for why the difference does not cause the new tobacco product to raise different questions of public health.

You have failed to provide sufficient information to support a finding of substantial equivalence; therefore, we are issuing an order finding that this new tobacco product is not substantially equivalent to an appropriate predicate tobacco product. Upon issuance of this order, your tobacco product is misbranded under section 903(a)(6) of the FD&C Act and adulterated under section 902(6)(A) of the FD&C Act. Failure to comply with the FD&C Act may result in FDA taking regulatory action without further notice. These actions may include, but are not limited to, civil money penalties, seizure, and/or injunction.

Additionally, FDA requests that within 15 days of this letter you submit a plan detailing the steps you plan to take to ensure that this misbranded and adulterated product is not further distributed, imported, sold, marketed, or promoted in the United States by others. Your plan should include information sufficient to distinguish this misbranded and adulterated product from legally marketed

tobacco products, including, but not limited to lot numbers, manufacturing codes, and manufacturing dates. The plan should also include a list of your direct accounts, and contain their contact information. Submit your plan to the address below with a cover letter that includes the following text in the subject line:

COMPLIANCE PLAN for SE0003206

FDA will post product identifying information on a list of tobacco products that are adulterated and misbranded due to an NSE order, available to the public at https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm371765.htm

We remind you that you are required to update your listing information in June and December of each year under section 905(i)(3) of the FD&C Act. As part of this listing update, under section 905(i)(3)(B) of the FD&C Act, you must provide information on the date of discontinuance and product identity for any product you discontinue.

If you wish to request supervisory review of this decision under 21 CFR 10.75, please submit the request via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[3] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter), or mail it 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 generally available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier 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 or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

We ask that your request be sent as a single submission with a cover letter that includes the following text in your subject line: **REQUEST FOR SUPERVISORY REVIEW for SE0003206**. In addition, we ask you to identify each basis for the request and include all information on which you wish your request to be based; it may not contain any new data or analysis that was not part of your SE Report.

**In order to legally market the new product described in this application, it must comply with the requirements in section 910(a)(2)(A) of the FD&C Act.**

See the following website for additional information on these three pathways:
https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/default.htm

[3] The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

If you have any questions, please contact Ester Hatton, Regulatory Health Project Manager, at (240) 402 - 4259.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2018.07.05 05:57:13 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products