DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

**May 20, 2015**

**NOT SUBSTANTIALLY EQUIVALENT**

Eagle River Importers, Inc.
Attention: Mr. Luis Figueredo, Attorney
Figueredo Law, P.A.
8455 Southwest 158th St
Miami, FL 33157

**FDA Submission Tracking Number (STN): SE0003618**

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**

| | |
|---|---|
| **Tobacco Product Manufacturer:** | Eagle River Importers, Inc. |
| **Tobacco Product Name[1]:** | North |
| **Tobacco Product Category:** | Cigarette |
| **Tobacco Product Sub-Category:** | Combusted, Filtered |
| **Package Type:** | Hard Box |
| **Package Quantity:** | Not Provided |
| **Characterizing Flavor:** | Not Provided |
| **Length:** | 84 mm |
| **Diameter:** | Not provided |
| **Filter Ventilation:** | Not provided |
| **Additional Identification:** | Cool Green |

[1] Brand/sub-brand or other commercial name used in commercial distribution

We have completed the review of your SE Report and have determined that it does not establish that the product specified above is substantially equivalent to the following predicate tobacco product:

**Predicate Tobacco Product**

| | |
|---|---|
| **Tobacco Product Manufacturer:** | Eagle River Importers, Inc. |
| **Tobacco Product Name[1]:** | North RYO Blend (2005) |
| **Tobacco Product Category:** | Roll-Your-Own Tobacco |
| **Tobacco Product Sub-Category:** | Roll-Your-Own Tobacco |
| **Package Type:** | Not Provided |
| **Package Quantity:** | Not Provided |
| **Characterizing Flavor:** | Not Provided |

We have described below our basis for this determination.

1. Your SE Report lacks information to uniquely identify the **new tobacco product**. Multiple products for the new tobacco product could exist due to differences in package quantity, length, width, characterizing flavor, or additional descriptors. For unique identification, *all* of the following is needed:

    a. Package quantity (e.g., 20 cigarettes per pack)
    b. Product diameter (e.g., 6.7 mm, 8.1 mm)
    c. Filter ventilation (e.g., none, 10%, 25%)
    d. Characterizing flavor (e.g., none, tobacco, menthol)

2. Your SE Report lacks information to uniquely identify the **predicate tobacco product**. Multiple products for the predicate tobacco product could exist due to differences in package quantity, length, width, characterizing flavor, or additional descriptors. For unique identification, *all* of the following is needed:

    a. Package type (e.g., soft pack, box)
    b. Package quantity (e.g., 20 cigarettes per pack)
    c. Characterizing flavor (e.g., none, tobacco, menthol)

3. Your SE Report lacks the basis for your determination that new tobacco product is substantially equivalent to the predicate tobacco product. You did not provide the basis for your determination that the new tobacco product either (1) has the same characteristics as the predicate tobacco product (in accordance with 910(a)(3)(A)(i) of the FD&C Act), or (2) has different characteristics than the predicate tobacco product but the new tobacco product does not raise different questions of public health (in accordance with section 910(a)(3)(A)(ii) of the FD&C Act). As a reminder,

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characteristics, as used in the definition of substantial equivalence, is defined at section 910(a)(3)(B) of the FD&C Act as "the materials, ingredients, design, composition, heating source, or other features of a tobacco product."

4. Your SE Report lacks an adequate summary of any health information related to your new tobacco product or a statement that such information will be made available upon request (section 910(a)(4) of the FD&C Act). Note that this requirement is separate from the requirement of section 904(a)(4) of the FD&C Act to submit certain health documents. You did not provide either an adequate summary of any health information or a statement that such information will be made available upon request.

5. Your SE Report lacks a side-by-side quantitative comparison of the new and predicate tobacco products with respect to "other features" as identified in section 910(a)(3)(B) of the FD&C Act. For example, your SE Report does not include any HPHC data. And, your SE Report does not contain a statement that there are no applicable "other features."

6. Your SE Report does not include side-by-side quantitative comparison of the new and predicate tobacco products with respect to heating sources.

7. Your SE Report lacks a statement of your action to comply with any standards under section 907 of the FD&C Act (see section 905(j)(1)(B) of the FD&C Act), including those standards under section 907(a) of the FD&C Act and any promulgated through regulation. For example, you did not provide a statement that the new tobacco product complies with the artificial or natural flavor ban in section 907(a)(1)(A).

8. Your SE Report lacks information to establish predicate eligibility (grandfathered status) for a tobacco product identified as the predicate product. The following information is needed to establish predicate eligibility:

    a. Evidence that demonstrates the predicate tobacco product was commercially marketed in the United States on February 15, 2007. Or, as alternative, evidence that the predicate tobacco product was commercially marketed, as close as possible to, both before and after February 15, 2007, could have been submitted. Examples of such evidence could have included, but not limited to, the following:

        - Dated copies of advertisements;
        - Dated catalog pages;
        - Dated promotional material;
        - Dated trade publications;
        - Dated bills of lading;
        - Dated freight bills;
        - Dated waybills;
        - Dated invoices;
        - Dated purchase orders;

- Dated customer receipts;
- Dated manufacturing documents;
- Dated distributor or retailer inventory lists;
- Any other document you believe demonstrates that the tobacco product was commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007.

If applicable, a brief statement explaining and identifying any citations or abbreviations (e.g., item number and/or product description) used in the evidence to reference the predicate tobacco products would be necessary.

b. A statement that the predicate tobacco product was not exclusively in a test market as of February 15, 2007
c. A complete description of the predicate tobacco product (as described above in Deficiency 2)
d. A brief description of how the predicate tobacco product is used by the consumer

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. Therefore, you must immediately stop all distribution, importation, sale, marketing, and promotion of your tobacco product in the United States. 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 SE0003618**

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 http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm339928.htm#2.

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 FDA Electronic Submission Gateway (www.fda.gov/esg) using eSubmitter, or mail to:

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

We request that your package be sent as a single submission with a cover letter that includes the following text in your subject line: **REQUEST FOR SUPERVISORY REVIEW for SE0003618**. In addition, we request that your package identify each basis for the request and contain 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.

**You may not legally market the new tobacco product described in this SE Report unless (1) FDA issues an order finding the product to be exempt from the requirements of substantial equivalence and you make the required submission under section 905(j)(1)(A)(ii) of the FD&C Act, (2) FDA issues an order finding the product substantially equivalent to a predicate tobacco product (section 910(a)(2)(A) of the FD&C Act), OR (3) FDA issues an order authorizing introduction or delivery for introduction into interstate commerce under a premarket tobacco application (section 910(c)(1)(A) of the FD&C Act).**

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

If you have any questions, please contact Cecilia Robinson, Regulatory Health Project Manager, at (240) 402 - 5881.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.05.20 16:35:01 -04'00'

David L. Ashley, PhD
RADM, US Public Health Service
Director, Office of Science
Office of Science
Center for Tobacco Products