DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 04, 2015

NOT SUBSTANTIALLY EQUIVALENT

Pacific Stanford Manufacturing Corporation
Attention: Daisy P. Arce, Notice Party
Unit 2507, 25/F
Tower 1, Cityland Condominium 10
6815 Ayala Avenue, Makati City
Philippines 1225

FDA Submission Tracking Number (STN): SE0002648

Dear Ms. Arce:

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:	Pacific Stanford Manufacturing Corporation
Tobacco Product Name[1]:	North
Tobacco Product Category:	Cigarette
Tobacco Product Sub-Category:	Not provided
Package Type:	Not provided
Package Quantity:	Not provided
Length:	Not provided
Diameter:	Not provided
Filter Ventilation:	Not provided
Characterizing Flavor:	Not provided

[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:	Not provided
Tobacco Product Name[2]:	Not provided
Tobacco Product Category:	Not provided
Tobacco Product Sub-Category:	Not provided
Package Type:	Not provided
Package Quantity:	Not provided
Length:	Not provided
Diameter:	Not provided
Filter Ventilation:	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 length, width, characterizing flavor, or additional descriptors. For unique identification of the new tobacco product, *all* of the following are needed:

    a. Product subcategory (e.g., filtered combusted, non-filtered combusted)
    b. Package type (e.g., hard pack, soft pack, clam shell)
    c. Package quantity (e.g., 20 per pack)
    d. Product length (e.g., 89 mm, 100 mm)
    e. Product diameter (e.g., 6.7 mm, 8.1 mm)
    f. Ventilation (e.g., none, 6.7 mm, 8.1 mm)
    g. Characterizing flavor (e.g., none, tobacco, menthol)
    h. Additional descriptor (e.g., none, blue, single wide)

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 length, width, characterizing flavor, or additional descriptors. For unique identification of the predicate tobacco product, *all* of the following are needed:

    a. Product name
    b. Product category (e.g., cigarette, roll-your-own, smokeless)

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

c. Product subcategory (e.g., filtered combusted, non-filtered combusted)
d. Package type (e.g., hard pack, soft pack, clam shell)
e. Package quantity (e.g., 20 per pack)
f. Product length (e.g., 89 mm, 100 mm)
g. Product diameter (e.g., 6.7 mm, 8.1 mm)
h. Ventilation (e.g., none, 6.7 mm, 8.1 mm)
i. Characterizing flavor (e.g., none, tobacco, menthol)
j. Additional descriptor (e.g., none, blue, single wide)

3. Your SE Report does not include all of the design parameters necessary to fully characterize the predicate and new tobacco products. In order to adequately characterize the products, it is necessary to compare key design parameters. The **target specifications and upper and lower range limits** for *all* the following cigarette design parameters for the predicate and new tobacco products were not provided:

   a. Cigarette length (mm)
   b. Cigarette circumference (mm)
   c. Cigarette draw resistance (mm H_2O)
   d. Tobacco filler mass (mg)
   e. Tobacco rod density (g/cm^3)
   f. Tobacco oven volatiles (OV) (%)
   g. Filter ventilation (%)
   h. Tipping paper length (mm)
   i. Cigarette paper base paper basis weight (g/m^2)
   j. Cigarette paper base paper porosity (CU)
   k. Cigarette paper band porosity (CU)
   l. Cigarette paper band width (mm)
   m. Cigarette paper band space (mm)
   n. 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)]
   o. Filter length (mm)
   p. Filter pressure drop (mm H_2O)

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

4. Your SE Report does not include any data confirming that specifications are met. *All* of the following **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 the predicate and new 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)

Certificates of analysis from the material supplier may satisfy this deficiency.

5. Your SE Report lacks any information regarding the heating source for the new and corresponding predicate products. A description of the heating source is necessary for product characterization as defined in section 910(a)(3)(B) of the FD&C Act.

6. Your SE Report lacks tobacco blend information other than tobacco leaf names and quantity in the new tobacco product. The limited information provided does not include sufficient detail to fully characterize the tobacco blend composition of the predicate and new tobacco 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 predicate and new products. *All* of the following items are needed for new and predicate tobacco products:

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

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

7. Your SE Report lists ingredients added to the tobacco with quantities for the new tobacco product. However, your SE Report does not include ingredients in all components of the predicate and new tobacco products. The ingredient information provided does not include sufficient detail to fully characterize the composition of the predicate and new tobacco products. *All* of the following would be needed to fully characterize the products:

   a. All ingredients used to manufacture the products, include individual ingredients in complex ingredients
   b. Quantities of all ingredients expressed in unit of measure, such as mass per cigarette

c. Information to uniquely identify each ingredient (e.g., CAS #, grade/purity, function)

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

8. Your SE Report lacks harmful and potentially harmful constituents (HPHC) data for the new and predicate tobacco products. HPHC data can provide useful evidence to demonstrate that the difference in product composition between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health. Because it is unclear what, if any, differences exist between the new and predicate tobacco products, it is unclear what HPHC data would be useful. However, if there are differences in product characteristics likely to affect HPHC quantities, then applicable HPHC data would be needed. For smoke analysis, the measurement of HPHC quantities under both ISO and Canadian Intense smoking regimens would best characterize the delivery of constituents from these products. *All* of the following information would be needed to evaluate the HPHC data:

    a. Quantitative test protocols and method used
    b. Testing laboratory and their accreditation(s)
    c. Length of time between date(s) of manufacture and date(s) of testing
    d. National/international standards used and any deviations(s) from those standards. If deviation(s) is not the same for methods used for the new and predicate products, provide scientific evidence demonstrating that the testing result for the new and predicate products are accurate and comparable
    e. Number of replicates
    f. Standard deviations
    g. Complete data sets
    h. A summary of the results for all testing performed
    i. Storage conditions prior to initiating testing

9. 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, 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."

10. 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.

11. 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).

12. 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 SE0002648

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.

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 SE0002648**. 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 Ryan Nguy, Regulatory Health Project Manager, at (301) 796 - 7079.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.09.04 09:27:11 -04'00'

David L. Ashley, Ph.D.
RADM, United States Public Health Service
Office of Science
Center for Tobacco Products