DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

August 06, 2015

NOT SUBSTANTIALLY EQUIVALENT

California Clinical Supply Company
Attention: Mr. Chris Hill, President
8228 W. Sunset Blvd
Suite 304
W. Hollywood CA 90046

FDA Submission Tracking Number (STN): SE0000515

Dear Mr. Chris Hill

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:	California Clinical Supply Company
Tobacco Product Name[1]:	CCS Papers
Tobacco Product Category:	Roll-Your-Own Tobacco
Tobacco Product Sub-Category:	Rolling Paper
Package Type:	Booklet
Package Quantity:	Not provided
Characterizing Flavor:	Not provided
Length:	Not provided
Width:	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 below is substantially equivalent to the following predicate tobacco product:

Predicate Tobacco Product

Tobacco Product Manufacturer:	California Clinical Supply Company
Tobacco Product Name[2]:	Chris Hill
Tobacco Product Category:	Roll-Your-Own Tobacco
Tobacco Product Sub-Category:	Rolling Paper
Package Type:	Booklet
Package Quantity:	Not provided
Characterizing Flavor:	Not provided
Length:	Not provided
Width:	Not provided

We have described below our basis for this determination.

1. Your SE Report provides information on the design parameters for the predicate and new products. However, 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, including the **target specifications and upper and lower range limits** for *all* of the following design parameters for the predicate and new tobacco products:

    a. Paper length (mm)
    b. Paper width (mm)
    c. Total mass (mg)
    d. Cigarette paper base paper basis weight (g/m^2)
    e. Cigarette paper base paper porosity (CU)
    f. Cigarette paper band porosity (CU) (if applicable)
    g. Cigarette paper band width (mm) (if applicable)
    h. Cigarette paper band space (mm) (applicable)

    For each of the above parameters, the values are needed on a per unit of product basis (e.g., paper length reported in mm per rolling paper). If a difference exists between the new and predicate tobacco products, a rationale for each difference in the target specification and range limits with evidence and a scientific discussion is needed for why the difference does not cause the new tobacco product to raise different questions of public health.

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

2. Your SE Report provides information on the design parameter specifications but does not include any 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** is needed for *all* of the following design parameters for the predicate and new tobacco products:

    a. Total mass (mg)
    b. Cigarette paper base paper basis weight (g/m^2)
    c. Cigarette paper base paper porosity (CU)
    d. Cigarette paper band porosity (CU) (if applicable)

    Certificates of analysis from the material supplier may satisfy this deficiency

3. Your SE Report describes the **new tobacco product** as "CSS papers"; however, you lack information to uniquely identify the tobacco product. Multiple products for the new product could exist due to differences in package quantity, length, width, characterizing flavor, or additional descriptors; thus, it is unclear whether the predicate product you are comparing to the new tobacco product is substantially equivalent. Your SE Report only contains identification of the product name, category, subcategory, and package type for the new product. For unique identification, *all* of the following information is needed:

    a. Package quantity (e.g., 50, 250 per booklet)
    b. Product length and width (e.g., 45 mm by 100 mm)
    c. Characterizing flavor (e.g., none, tobacco, menthol)
    d. Additional descriptor (e.g., none, blue, single wide)

4. Your SE Report describes the **predicate tobacco product** as "Chris Hill"; however, you lack information to uniquely identify the tobacco product. Multiple products for the predicate product could exist due to differences in package quantity, length, width, characterizing flavor, or additional descriptors; thus, it is unclear whether the predicate product you are comparing to the new tobacco product is substantially equivalent. Your SE Report only contains identification of the product name, category, subcategory, and package type for the predicate product. For unique identification, *all* of the following information is needed:

    a. Package quantity (e.g., 50, 250 per booklet)
    b. Product length and width (e.g., 45 mm by 100 mm)
    c. Characterizing flavor (e.g., none, tobacco, menthol)
    d. Additional descriptor (e.g., none, blue, single wide)

5. Your SE Report does not provide ingredients other than fiber species added to the predicate and new tobacco products. The ingredient information in the SE Report is not adequate to fully characterize the composition of the predicate and new tobacco products because it does not include *all* of the following information:

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

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

6. Your SE Report provides information about the fiber ingredients for samples analyzed by (b) (4)
However, the information does not clearly identify the samples that were analyzed (e.g., #1 Primary Analysis, #2 Compare, #3 Compare, and #4 Compare) and how they correspond to the new and predicate tobacco products.

7. Your SE Report lacks the basis for your determination that the new tobacco product is substantially equivalent to a predicate tobacco product. Your basis should specify that the new tobacco product either (1) has the same characteristics as the predicate tobacco product (in accordance with section 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."

8. Your SE Report lacks information to establish predicate eligibility (grandfathered status) for the 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 an alternative, evidence that the predicate tobacco product was commercially marketed as close as possible to, both before and after, February 15, 2007, could be submitted. Examples of such evidence may include, but is 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 product.

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 the unique identification deficiency)
d. A brief description of how the predicate tobacco product is used by the consumer

If you have submitted this information in a stand-alone GF submission, this deficiency could be satisfied by providing the submission tracking number of the GF submission.

9. 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) to submit certain health documents.

10. Your SE Report lacks a statement of your action to comply with any standards under section 907 (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.

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 SE0000515

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/TobaccoProductReviewEvaluation/NewTobaccoProductReviewandEvaluation/ucm371765.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.

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 SE0000515**. 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 Kim C. Collins, Lead Regulatory Health Project Manager, at (301) 796-1556.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.08.06 16:41:41 -04'00'

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