Technical Project Lead (TPL) Review: SE0000515

SE0000515: "CCS Papers"[1]	
Package Type	Booklet
Package Quantity	Not provided
Length	Not provided
Width	Not provided
Characterizing Flavor	Not provided
Common Attributes of SE Reports	
Applicant	California Clinical Supply Company
Report Type	Provisional
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Rolling Paper
Recommendation	
Issue a Not Substantially Equivalent (NSE) Order.	

[1] Because of the paucity of information about the new tobacco product in the SE Report, the product name varied in previous FDA documents, including letters to the applicant. The product name captured in this TPL review reflects that name stated on the cover letter of the SE Report.

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S
Date: 2015.08.05 17:11:05 -04'00'

Matthew R. Holman, Ph.D.
Director
Division of Product Science

Signatory Decision:

☒ Concur with TPL recommendation and basis of recommendation

☐ Concur with TPL recommendation with additional comments (see separate memo)

☐ Do not concur with TPL recommendation (see separate memo)

Digitally signed by David Ashley -S
Date: 2015.08.05 19:15:15 -04'00'

David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
Director
Office of Science

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0000515	"CCS Papers"
Product Name	"Chris Hill"[2]
Package Type	Booklet
Package Quantity	Not provided
Length	Not provided
Width	Not provided
Characterizing Flavor	Not provided

The predicate tobacco product is roll-your-own tobacco rolling paper manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted the original SE Report on March 1, 2011. Acknowledgement letters were issued on September 21, 2011, and November 17, 2011[3]. On August 25, 2011, FDA conducted a jurisdiction review. The SE Report was found administratively incomplete after conducting a completeness review on December 20, 2012, and FDA issued an Advice/Information (A/I) request letter that same day. FDA attempted to contact Mr. Chris Hill via telephone on December 3rd, December, 10th and December 20th to discuss product list information. Voice messages were left by FDA for Mr. Hill, with no return telephone call received by FDA. The A/I letter was returned as undeliverable by the U.S. Postal Service on December 29, 2012. On March 17, 2014, FDA conducted a Public Health Impact (PHI) review. A Public Health Impact (PHI) Advice/Information (A/I) request letter was issued for this SE Report on May 10, 2013. The PHI A/I letter was not returned, and the applicant did not respond to FDA's A/I request. Based on the review order determined by PHI Review and randomization schema, on August 11, 2014, FDA issued a notification letter. This letter noted that scientific review was to begin on September 25, 2014, and that FDA would review all amendments received no later than September 24, 2014. On August 26, 2014, FDA called Mr. Hill as a follow up to the Notification letter issued on August 11, 2014, and a voice message was left, but this call was not returned. The Notification letter was returned as undeliverable by the UPS (United Parcel Service) on August 22, 2014. On September 17, 2014, FDA called Mr. Hill and a voice

[2] Because of the paucity of information about the predicate tobacco product in the SE Report, the product name varied in previous FDA documents, including letters to the applicant. The product name captured in this TPL review reflects that name stated on the cover letter of the SE Report.

[3] Both acknowledgement letters are identical except the signature block and address. A second acknowledgement letter issued as the first letter was returned. The second acknowledgment letter includes a suite number in the address.

message was left, but this call was not returned. On October 9, 2014, FDA called Mr. Hill to notify him of a change in project manager assigned to his SE Report and a voice message was left, but this call was not returned. On December 10, 2014 with follow-up on December 12, 2014, FDA called Mr. Hill to verify the correct mailing address and to instruct him to submit the requested information to the CTP Document Control Center. On March 4, 2015, FDA called Mr. Hill to verify the correct mailing address and to instruct him once again to submit a formal change of address to the CTP Document Control Center. Due to the new and predicate products not being uniquely identified, a Preliminary Finding letter was issued on March 19, 2015, with a response due date of April 19, 2015. On March 19, 2015, FDA called Mr. Hill to notify him of the Preliminary Finding letter. The Preliminary Finding letter was returned as undeliverable by the UPS (United Parcel Service) on March 24, 2015. On April 21 and April 24, 2015, FDA called Mr. Hill on alternate telephone numbers to notify him of the Preliminary Finding letter and verify the applicant's mailing address. To date, Mr. Hill has not returned any of FDA's telephone calls concerning SE0000515. FDA has not received any amendments in response to any issued letters nor received any formal requests to withdraw the SE Report. Based on the lack of response to multiple Advice/Information requests and phone calls, the applicant is considered a non-responder, and the SE Report is being handled accordingly.[4] Further analysis of this SE Report identified that, in addition to being administratively incomplete, evidence to demonstrate grandfathered status of the predicate tobacco product and scientific information to assess differences in product characteristics were both missing.

Product Name	SE Report	Amendments
Roll-Your-Tobacco Rolling Paper	SE0000515	none

1.3. SCOPE OF REVIEW

This review captures all administrative, compliance, and scientific reviews completed for this SE Report.

2. ADMINISTRATIVE REVIEW

An administrative completeness review was completed by Ouida Holmes on December 20, 2012.

[4] See the September 5, 2014, memorandum by Cristi Stark describing OS's criteria for defining a non-responder and OS's process for handing provisional SE Reports from applicants who are non-responders.

The completeness review concluded that the SE Reports are *not* administratively complete because the SE Reports were missing the following information:

- New tobacco product not uniquely identified
- Predicate tobacco products not uniquely identified
- No statement of basis for applicant's claims of substantial equivalence
- No health information summary or statement that such information would be provided upon request
- No side-by-side quantitative comparison new and predicate tobacco products with respect to "other features" (or statement that this is not applicable)
- No side-by-side quantitative comparison new and predicate tobacco products with respect to heating source (or statement that this is not applicable)
- No statement of compliance with standards under section 907 of the FD&C Act
- No environmental assessments

A regulatory review was completed by Kim Collins on March 18, 2015. This review recommended issuance of a Preliminary Finding letter due to multiple deficiencies within the reports. The review noted that deficiencies regarding unique identification of the new and predicate tobacco products, "other features," and the heating source would be addressed during scientific review. However, in addition to administrative incompleteness, there was a lack of evidence to demonstrate the predicate product was commercially marketed in the United States as of February 15, 2007. Therefore, the following deficiency was added to the Preliminary Finding letter:

1. 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, submit 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, you may satisfy this deficiency by providing the submission tracking number of the GF submission.

Before submitting your response, we suggest that you contact CTP's Office of Compliance and Enforcement so that they can help you satisfy their request for additional information. This will allow them to assist you in the furtherance of your submission in a more productive manner.

To date, FDA has not received any amendments in response to any issued letters nor received any formal requests to withdraw the SE Reports. It should be noted that deficiency regarding "other features" was not included in the March 19, 2015, Preliminary Finding letter, as it was addressed during scientific review. Deficiencies regarding the heating source and environmental assessment were inadvertently omitted from the March 19, 2015, Preliminary Finding letter. However, all other issues identified in the completeness review were conveyed in the March 19, 2015, Preliminary Finding letter. As the SE Reports are still deficient, the lack of an environmental assessment does not need to be conveyed to the applicant in the order letters; an environmental assessment was prepared by FDA on November 14, 2013, to evaluate the impact of issuing NSE orders.

It should be noted that the regulatory review concluded that there was inadequate information to proceed with substantive scientific review. However, OS did initiate substantive scientific review because the SE Report includes minimal information about the characteristics of the new and predicate tobacco products such that it was not possible to determine whether there are any differences in product characteristics between the new and predicate tobacco products. Conducting the

scientific review resulted in the issuance of a Preliminary Finding letter that provides a more comprehensive list of missing information necessary to understand product characteristics and determine substantial equivalence of the new and predicate tobacco product. The scientific review was limited to chemistry and engineering because these are the two disciplines that are responsible for ensuring that FDA has the basic characteristics related to product composition and design. Because the information in the SE Report is very limited, these reviews were completed shortly after the regulatory review was completed.

3. COMPLIANCE REVIEW

Compliance reviews were not completed because information to uniquely identify the predicate tobacco product was not provided in the SE Reports. However, a deficiency related to the evidence needed to establish grandfathered status of the predicate tobacco product was included in the March 18, 2015, regulatory review (see Section 2 of this review).

4. SCIENTIFIC REVIEW

Scientific reviews were completed by the Office of Science (OS) for the following disciplines:

4.1. CHEMISTRY

A chemistry review was completed by Kimberly Agnew-Heard on February 11, 2015.

The chemistry review concludes that there is insufficient information to determine the product characteristics of the new and predicate tobacco products and, as such, whether there are any differences in characteristics related to product composition. The review identifies the following deficiencies that have *not* been adequately resolved:

1. Your SE Report describes the **new tobacco product** as “private-label roll-your-own cigarette paper in booklet form”; 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, submit *all* of the following:

    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)

In your response, it is necessary to address each item above, if any of the items listed does not apply, provide the statement "Not Applicable."

2. Your SE Report describes the **predicate tobacco product** as "private-label roll-your-own cigarette paper in booklet form"; 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, submit *all* of the following:

    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)

    In your response, it is necessary to address each item above, if any of the items listed does not apply, provide the statement "Not Applicable."

3. Your SE Report does not provide ingredients other than fiber species added to the predicate and new products. The information provided for the fiber analysis does not include sufficient detail to fully characterize the composition of the predicate and new products. Provide *all* of the following for the new and predicate 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 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 products, provide a rationale for each difference with evidence and a scientific rationale for why the difference does not cause the new product to raise different questions of public health.

4. Your SE Report provides information about the fiber ingredients for samples analyzed by [redacted]. However, the information does not clearly identify the

samples that were analyzed. Identify and clarify the sample code names (e.g., #1 Primary Analysis, #2 Compare, #3 Compare, and #4 Compare) that correspond to the new and predicate products.

Therefore, the applicant has failed to demonstrate that the differences in product characteristics related to product composition between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

It should be noted that Deficiency 1 and Deficiency 2 identify the names of the new and predicate tobacco products as “private-label roll-your-own cigarette paper in booklet form,” but this is not a product name (i.e., not a brand/sub-brand name). Therefore, both deficiencies should include product name on the list of information required to uniquely identify the new and predicate tobacco products.

4.2. ENGINEERING

An engineering review was completed by Erdit Gremi on February 11, 2015.

The engineering review concludes that there is insufficient information to determine the product characteristics of the new and predicate tobacco products and whether there are any differences in characteristics related to product design. The review identifies the following deficiencies that have *not* been adequately resolved:

1. Your SE Report provides minimal information on the design parameters for the predicate and new products. However, your SE Reports do not include all of the design parameters necessary to fully characterize the predicate and new products. In order to adequately characterize the products, it is necessary to compare key design parameters. Provide the **target specifications and upper and lower range limits** for *all* of the following rolling paper design parameters for each predicate and new product:

    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); and
    h. Cigarette paper band space (mm) (applicable).

    For each of the above parameters, provide the necessary data on a per unit of product basis (e.g., paper length should be reported in mm per rolling paper). If a design parameter is not applicable (e.g., band porosity

if the cigarette paper does not contain bands), state as such and provide a scientific rationale.

If a difference exists between the new and corresponding predicate products, provide a rationale 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 product to raise different questions of public health.

2. Your SE Report provides minimal information on the design parameter specifications but do not include any data confirming that specifications are met. Provide the **test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results** for *all* of the following rolling paper design parameters for each predicate and new product:

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

    If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), state as such and provide a scientific rationale.

    Certificates of analysis from the material supplier may satisfy this deficiency. If you choose to address this deficiency by providing certificates of analysis for any of the parameters listed above, the certificates of analysis must include a 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.

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

Therefore, the applicant has failed to demonstrate that the differences in product characteristics related to product design between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by RADM David L. Ashley on November 19, 2013. The FONSI was supported by an environmental assessment prepared by FDA on November 14, 2013.

6. CONCLUSION AND RECOMMENDATION

The key differences in characteristics between the new and predicate tobacco products are unknown because the SE Report contains essentially no information about the characteristics of the new and predicate tobacco products. Therefore, the applicant failed to provide sufficient information to support a finding of substantial equivalence.

The predicate tobacco product does not meet statutory requirements, as the applicant has not demonstrated that the predicate tobacco product is grandfathered product (i.e., was commercially marketed in the United States as of February 15, 2007).

FDA examined the environmental effects of finding this new tobacco product not substantially equivalent and made a finding of no significant impact.

An NSE order letter should be issued for the new tobacco product in SE0000515, as identified on the cover page of this review. The NSE order letter should cite the following deficiencies:

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. 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 grandfathered ("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.