Technical Project Lead (TPL) Memorandum:

SE Reports SE0003441, SE0003442, SE0003443, SE0003444

SE0003441: Sutra Bidis Red	
Package Size	Not provided
Package Type	Not provided
SE0003442: Sutra Bidis Menthol	
Package Size	Not provided
Package Type	Not provided
SE0003443: Sutra Bidis Red Cone	
Package Size	Not provided
Package Type	Not provided
SE0003444: Sutra Bidis Menthol Cone	
Package Size	Not provided
Package Type	Not provided
Common Attributes of SE Reports	
Applicant	Jash International, Inc.
Report Type	Provisional
Product Category	Cigarette
Product Sub-Category	Bidi
Recommendation	
Issue Not Substantially Equivalent (NSE) orders	

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S
Date: 2014.02.20 15:14:56 -05'00'

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: 2014.02.20 15:34:28 -05'00'

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 PRODUCTS

The applicant submitted the following predicate tobacco products:

Table 1. Predicate Tobacco Products

Sutra Bidis Red (SE0003441)	
Product Name	Not provided
Package Size	Not provided
Sutra Bidis Menthol (SE0003442)	
Product Name	Not provided
Package Size	Not provided
Sutra Bidis Red Cone (SE0003443)	
Product Name	Not provided
Package Size	Not provided
Sutra Bidis Menthol Cone (SE0003444)	
Product Name	Not provided
Package Size	Not provided

1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted 4 SE Reports listed in Table 2 of this memorandum on March 21, 2011. FDA sent the applicant administrative advice and information request letters (A/I letters) for these SE Reports on March 19, 2013. The applicant did not respond to the administrative A/I letter. However, a series of teleconferences occurred between FDA and the authorized agent to try to clarify the information in the reports and to receive necessary information for FDA to carry out review. FDA contacted the authorized agent, Mr. Barry Boren, on March 15, 2013, March 19, 2013, and April 3, 2013. These teleconferences were to determine the new tobacco products that Mr. Boren had submitted for review, the predicate tobacco products for comparison, and the first date of commercial marketing in the United States for the new tobacco products subject of the provisional SE Reports. Mr. Boren clarified that he did not have an exact date for commercial marketing for the four Sutra products; however, they were imported and sold in the United States as of June 2009. In addition, on April 12, 2013, Mr. Boren contacted FDA and stated he had sent a letter back to his client in India with FDA's information requests; however, he has not yet heard back from his client with the requested information. As some of the requested information is unique identification of the new and predicate tobacco products, FDA was unable to begin the determination of grandfathered status or scientific review. Therefore, in July 2013, FDA sent a preliminary finding letter to the applicant. FDA called Mr. Boren on August 5, 2013, to confirm receipt of the preliminary finding letter, and on August 23, 2013 to remind him of the due date for additional information requested in the preliminary finding letter. Mr. Boren stated that Jash considered (b) (4) during the August 5, 2013 phone call,

but at the time of the August 23, 2013, follow up call, he stated they would not respond. The due date for the requested information in the preliminary finding letter was August 24, 2013, and the applicant has not responded.

Table 2. SE Reports and Amendments

Product Name	SE Report	Amendments
Sutra Bidis Red	SE0003441	none
Sutra Bidis Menthol	SE0003442	none
Sutra Bidis Red Cone	SE0003443	none
Sutra Bidis Menthol Cone	SE0003444	none

1.3. SCOPE OF MEMO

This memo captures all administrative, compliance, and scientific reviews completed for SE0003441, SE0003442, SE0003443, and SE0003444.

1.4. KEY DIFFERENCES BETWEEN NEW AND PREDICATE TOBACCO PRODUCTS

The key differences between new and corresponding predicate tobacco products are unknown because the SE Reports do not identify the predicate tobacco products. Furthermore, the SE Reports are devoid of any information about the characteristics of the new and predicate tobacco products.

2. ADMINISTRATIVE REVIEW

Administrative completeness reviews for these four SE Reports were completed by Joanna Randazzo, D.C. on March 19, 2013. The administrative completeness reviews for all four SE Reports concluded that these SE Reports are not administratively complete. On July 24, 2013, Cristi Stark, M.S. drafted a memorandum concerning these SE Reports. The memorandum concluded that, because some of the requested information is required for unique identification of the new and predicate tobacco products, FDA cannot begin the determination of grandfathered status or scientific review. The memorandum, therefore, recommended that a preliminary finding letter be issued to the applicant. Based on the administrative completeness reviews and memorandum, the preliminary finding letter included the following deficiencies:

1. All four of your SE Reports lack information to fully identify the new tobacco products. Submit *all* of the following for each SE Report:

    a. Product name (brand and subbrand)
    b. Category (i.e., cigarette, smokeless tobacco, cigarette tobacco, roll-your-own tobacco)

c. Subcategory (e.g., moist snuff, filtered conventional cigarette, bidi)
d. Package type (e.g., soft pack, hard pack)
e. Package size (mass or, if portioned, count)
f. Portion size, if applicable (mass)

2. All four of your SE Reports lack information to fully identify the predicate tobacco products. Submit *all* of the following for each SE Report:

   a. Product name (brand and subbrand)
   b. Category (i.e., cigarette, smokeless tobacco, cigarette tobacco, roll-your-own tobacco)
   c. Subcategory (e.g., moist snuff, filtered conventional cigarette, bidi)
   d. Package type (e.g., soft pack, hard pack)
   e. Package size (mass or, if portioned, count)
   f. Portion size, if applicable (mass)

3. All four of your SE Reports lack information needed in order for FDA to determine whether or not the new tobacco products are substantially equivalent to the corresponding predicate tobacco products. Submit the characteristics for all of your predicate and new products and any information needed to demonstrate whether the characteristics of the new and corresponding predicate products are the same or different. If there are different characteristics between the new and corresponding predicate products, provide evidence and scientific rationale as to why each difference in characteristic does not cause the new product to raise different questions of public health.

4. All four of your SE Reports lack an adequate summary of health information (Section 910(a)(4)(B) of the FD&C Act) related to your new tobacco product or a statement that it will be made available upon request (Section 910(a)(4)(A) of the FD&C Act). If the summary is included it should contain detailed information on data concerning adverse health effects and information related to the new tobacco product, i.e., not be limited to results of studies on this new tobacco product. Please note that this requirement is separate from the requirement of Section 904(a)(4) to submit certain health documents. Provide either an adequate summary of summary of health information or a statement that it will be made available upon request.

5. All four of your SE Reports lack a statement of your action to comply with the requirements of 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. If any of the standards are not applicable to your new products, provide a statement to that effect. Provide the appropriate statement.

6. All four of your SE Reports lack information needed in order for FDA to make a determination as to whether or not the tobacco products you have referenced as a predicate is predicate-eligible (grandfathered status).

    a. Provide evidence that demonstrates the predicate tobacco products were commercially marketed in the United States on February 15, 2007. If you cannot provide evidence demonstrating the tobacco products were commercially marketed on February 15, 2007, we suggest that you provide evidence that the predicate tobacco products were commercially marketed, as close as possible to, both before and after February 15, 2007.

    Examples of such evidence may include, but are 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.

    Provide 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.

    b. Provide a statement that the predicate tobacco products were not exclusively in a test market as of February 15, 2007.

    c. Specify the predicate tobacco products type, i.e., cigarette, smokeless tobacco, cigarette tobacco, roll-your-own tobacco. If the products are cigarettes, provide a brief statement as to whether the predicate tobacco products were packaged in soft or hard pack. In addition, provide a brief description of how the predicate tobacco products are used by the consumer.

At this time, the applicant has not responded to the preliminary finding letter. Therefore, the applicant has not demonstrated that the new and predicate tobacco products are substantially equivalent.

3. PUBLIC HEALTH IMPACT (PHI) REVIEW

Because these SE Reports are provisional[1], PHI reviews were carried out for them. PHI reviews were completed by Brian Connell, Ph.D. on September 15, 2012, for these four SE Reports. The reviews concluded that these reports should be assigned to PHI Tier 1, meaning that they are high priority for scientific review.

4. COMPLIANCE REVIEW

Because the SE Reports do not identify predicate tobacco products, the Office of Compliance and Enforcement (OCE) did not complete reviews to determine whether the applicant established that the predicate tobacco products are grandfathered products (i.e., were commercially marketed as of February 15, 2007). Similarly, because the new tobacco products are not substantially equivalent to the predicate tobacco products, OCE did not complete a review to determine whether the new tobacco products are in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as required by section 910(a)(2)(A)(i)(II) of the FD&C Act.

5. SCIENTIFIC REVIEW

Scientific reviews were not completed because the SE Reports do not uniquely identify the new and predicate tobacco products. Furthermore, the SE Reports are devoid of any information about the characteristics of the new and predicate tobacco products.

6. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by RADM David L. Ashley on June 10, 2013, based on a programmatic environmental assessment for agency determinations that products were not substantially equivalent. The programmatic environmental assessment was prepared by Hoshing Chang, Ph.D., on May 29, 2013.

7. CONCLUSION AND RECOMMENDATION

The key differences between new and corresponding predicate tobacco products are unknown because the SE Reports do not identify the predicate tobacco products.

[1] SE Reports were submitted on or prior to March 22, 2011, and the new tobacco products subject of these reports were marketed on or prior to March 22, 2011 (section 910(a)(2)(B) of the FD&C Act).

Furthermore, the SE Reports are devoid of any information about the characteristics of the new and predicate tobacco products.

The memorandum by Cristi Stark, M.S. on July 24, 2013, concluded that, because some of the requested information is required for unique identification of the new and predicate tobacco products, FDA cannot begin the determination of grandfathered status or scientific review. I concur with this conclusion. Because the applicant has not provided this information, the new tobacco products are not substantially equivalent.

The applicant did not provide a health information summary. To fulfill the provisions of section 910(a)(4) of the FD&C Act, the applicant must submit a health information summary or state that it will make such information available upon request by any person.

An order letter can be issued because FDA examined the environmental effects of finding these new tobacco products not substantially equivalent and made a finding of no significant impact.

The NSE order letters should be issued for the new tobacco product in SE0003441, SE0003442, SE0003443, and SE0003444, as identified on the cover page of this memorandum. Each of the NSE order letters should cite the following deficiencies:

1. Your SE Report lacks information to fully identify the new tobacco product. A*ll* of the following is need to fully identify the product:

    a. Product name (brand and subbrand)
    b. Category (i.e., cigarette, smokeless tobacco, cigarette tobacco, roll-your-own tobacco)
    c. Subcategory (e.g., moist snuff, filtered conventional cigarette, bidi)
    d. Package type (e.g., soft pack, hard pack)
    e. Package size (mass or, if portioned, count)
    f. Portion size, if applicable (mass)

2. Your SE Report lacks information to fully identify the predicate tobacco product. A*ll* of the following is need to fully identify the product:

    a. Product name (brand and subbrand)
    b. Category (i.e., cigarette, smokeless tobacco, cigarette tobacco, roll-your-own tobacco)
    c. Subcategory (e.g., moist snuff, filtered conventional cigarette, bidi)
    d. Package type (e.g., soft pack, hard pack)
    e. Package size (mass or, if portioned, count)
    f. Portion size, if applicable (mass)

3. Your SE Report lacks information needed in order for FDA to determine whether or not the new tobacco products are substantially equivalent to the corresponding predicate tobacco products. The characteristics of the predicate and new tobacco products were not included in the SE Report. In addition to the characteristics, there would need to be scientific evidence and rationale for why each difference in characteristics between the new and predicate product does not cause the new product to raise different questions of public health.

4. Your SE Report lacks an adequate summary of health information (section 910(a)(4)(B) of the FD&C Act) related to your new tobacco product or a statement that it will be made available upon request (section 910(a)(4)(A) of the FD&C Act).

5. Your SE Report lacks a statement of your action to comply with the requirements of 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) and any promulgated through regulation. If any of the standards are not applicable to your new products, then a statement to that effect would be required.

6. Your SE Report lacks information to establish predicate eligibility (grandfather status) for a tobacco product identified as the predicate. 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