DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville, MD 20850-3229

February 21, 2014

NOT SUBSTANTIALLY EQUIVALENT

Jash International, Inc.
Attention: Barry M. Boren, Law Offices of Barry M. Boren
9100 South Dadeland Blvd., Suite 1809
Miami, FL 33156
via UPS

Submission Tracking Number (STN): SE0003443

Dear Mr. Boren:

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 Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Applicant:	Jash International, Inc.
Tobacco Product Name[1]:	Sutra Bidis Red Cone
Tobacco Product Category:	Cigarette
Tobacco Product Sub-Category:	Bidi
Package Size:	Not provided
Package Type:	Not provided

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 a predicate tobacco product. We have described below our basis for this determination.

1. Your SE Report lacks information to fully identify the new tobacco product. *All* of the following is needed 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)

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

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. *All* of the following is needed 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 (grandfathered 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

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) 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 SE0003443.

FDA will post product identifying information on a list of tobacco products that are adulterated and misbranded due to an NSE order. This list can be found by visiting FDA's website at www.fda.gov/tobacco and searching for "Misbranded and Adulterated NSE Tobacco Products" using the search box.

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 seek further FDA review of this decision, we suggest that you first request a meeting with the FDA staff who reviewed your submission. 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:

Center for Tobacco Products
Food and Drug Administration
Document Control Center, Rm 020J
9200 Corporate Boulevard
Rockville, MD 20850-3229

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 SE0003443**. 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), (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/NewTobaccoProductReviewandEvaluation/default.htm.

If you have any questions, please contact Joanna Randazzo, D.C., Regulatory Health Project Manager, at (240) 402 - 5216.

Sincerely,

Digitally signed by David Ashley -S
Date: 2014.02.21 08:38:18 -05'00'

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