



U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

September 28, 2021

SUBSTANTIALLY EQUIVALENT

Soex India Pvt. LTD
Attention: James W. Woodlee, Partner
Kleinfeld, Kaplan & Becker LLP
1850 M Street NW, Suite 800
Washington, DC 20036

FDA Submission Tracking Numbers (STNs): Multiple STNs, see Appendix A

Dear Mr. Woodlee:

We completed our review of your SE Reports¹ and determined that the new tobacco products are substantially equivalent to the corresponding predicate tobacco products listed in Appendix A and are in compliance with the requirements of the FD&C Act. Under the provisions of section 910 and 905(j) of the FD&C Act, you may introduce or deliver for introduction into interstate commerce the new tobacco products subject of this letter.

Our finding does not mean we “approved” the new products specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco products specified in Appendix A, or the labeling, as being “approved” by FDA (see Section 301(tt) of the FD&C Act).

For information on how to fulfill the provisions of section 910(a)(4) of the FD&C Act, refer to Appendix B.

In accordance with 40 CFR 1506.6, we will make your Environmental Assessment (EA) publicly available.

All regulated tobacco products, including the tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure the tobacco products specified in Appendix A complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

¹ Substantially Equivalent (SE) Reports submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Multiple STNs, see Appendix A

Page 2 of 5

If you have any questions, please contact Rodney Hammond, Regulatory Health Project Manager, at (301) 796-4667 or Rodney.Hammond@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S

Date: 2021.09.28 10:23:52 -04'00'

Matthew R. Holman, Ph.D.

Director

Office of Science

Center for Tobacco Products

Enclosures:

Appendix A – New and Corresponding Predicate Tobacco Products Subject of This Letter

Appendix B – Health Information Summary

Appendix A
New and Corresponding Predicate Tobacco Products Subject of This Letter

Common Attributes of SE Reports		
Submission date	September 8, 2020	
Receipt date	September 8, 2020	
Product manufacturer	Soex India Pvt. LTD	
Product category	Waterpipe Tobacco Products	
Product subcategory	Waterpipe Tobacco Filler	
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021810	GF2009766
Product name	Afzal Hookah Molasses Blueberry (1000 grams) ²	Afzal Hookah Molasses Blueberry 250g (Package) ²
Eligibility status	Not applicable	Grandfathered
Package type	Pouch	Pouch
Package quantity	1000 grams	250 grams
Characterizing flavor	Blueberry	Blueberry
STN	SE0023367	GF2009763
Product name	Afzal Hookah Molasses Double Apple (1000 grams) ²	Afzal Hookah Molasses Double Apple 250g (Package) ²
Eligibility status	Not applicable	Grandfathered
Package type	Pouch	Pouch
Package quantity	1000 grams	250 grams
Characterizing flavor	Apple	Double Apple
STN	SE0023368	GF2009782
Product name	Afzal Hookah Molasses Dubai Mint (1000 grams) ²	Afzal Hookah Molasses Pudina 250g (Package) ²
Eligibility status	Not applicable	Grandfathered
Package type	Pouch	Pouch
Package quantity	1000 grams	250 grams
Characterizing flavor	Mint	Pudina (translated as Mint)
STN	SE0023369	GF2009778
Product name	Afzal Hookah Molasses Golden Amber (1000 grams) ²	Afzal Hookah Molasses Golden Amber 50g (Package) ²
Eligibility status	Not applicable	Grandfathered
Package type	Pouch	Pouch
Package quantity	1000 grams	50 grams
Characterizing flavor	None	None

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

STN	SE0023370	GF2009792
Product name	Afzal Hookah Molasses Mint (1000 grams) ²	Afzal Hookah Molasses Mint 50g (Package) ²
Eligibility status	Not applicable	Grandfathered
Package type	Pouch	Pouch
Package quantity	1000 grams	50 grams
Characterizing flavor	Mint	Mint
STN	SE0023371	GF2009788
Product name	Afzal Hookah Molasses Mixed Fruit (1000 grams) ²	Afzal Hookah Molasses Mixed Fruit 250g (Package) ²
Eligibility status	Not applicable	Grandfathered
Package type	Pouch	Pouch
Package quantity	1000 grams	250 grams
Characterizing flavor	Mixed Fruit	Mixed Fruit
STN	SE0023372	GF2009754
Product name	Afzal Hookah Molasses Orange (1000 grams) ²	Afzal Hookah Molasses Orange 50g (Package) ²
Eligibility status	Not applicable	Grandfathered
Package type	Pouch	Pouch
Package quantity	1000 grams	50 grams
Characterizing flavor	Orange	Orange
STN	SE0023375	GF2009751
Product name	Afzal Hookah Molasses Peach (1000 grams) ²	Afzal Hookah Molasses Peach 250g (Package) ²
Eligibility status	Not applicable	Grandfathered
Package type	Pouch	Pouch
Package quantity	1000 grams	250 grams
Characterizing flavor	Peach	Peach
STN	SE0023376	GF2009794
Product name	Afzal Hookah Molasses Strawberry (1000 grams) ²	Afzal Hookah Molasses Strawberry 250g (Package) ²
Eligibility status	Not applicable	Grandfathered
Package type	Pouch	Pouch
Package quantity	1000 grams	250 grams
Characterizing flavor	Strawberry	Strawberry

STN	SE0023377	GF2009771
Product name	Afzal Hookah Molasses Watermelon (1000 grams) ²	Afzal Hookah Molasses Watermelon 50g (Package) ²
Eligibility status	Not applicable	Grandfathered
Package type	Pouch	Pouch
Package quantity	1000 grams	50 grams
Characterizing flavor	Watermelon	Watermelon
STN	SE0023595	GF2009760
Product name	Afzal Hookah Molasses Mango (1000 grams) ²	Afzal Hookah Molasses Mango 50g (Package) ²
Eligibility status	Not applicable	Grandfathered
Package type	Pouch	Pouch
Package quantity	1000 grams	50 grams
Characterizing flavor	Mango	Mango

Appendix B

Health Information Summary

Your SE Reports did not provide a summary of any health information related to the new tobacco products, required by section 910(a)(4) of the FD&C Act; however, your SE Reports stated that such information will be available upon request to any person. Consistent with the requirements of section 910(a)(4), you may wish to consider providing the following when information is requested:

- A. A copy of your final SE Reports upon which the Substantially Equivalent order was based, redacted only to the extent necessary to exclude patient identifiers and trade secret and confidential commercial information as defined in 21 CFR 20.61 and 20.63.
- B. Any research or data you have in your possession or otherwise know of specifically regarding the adverse health effects of the new tobacco products, or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name].”

Alternatively, you may provide the following when information is requested:

- Description of the new tobacco products
- Description of the predicate tobacco products
- List of all differences in characteristics between the new and predicate tobacco products
- Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise different questions of public health
- Any research or data you have in your possession or otherwise know of regarding the adverse health effects of the new tobacco product, or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name].”

There may be other accurate, complete, and not false or misleading ways to satisfy the requirements of section 910(a)(4) not included above. If you wish to discuss other ways to meet the requirements of section 910(a)(4), submit a meeting request to us.