

Technical Project Lead (TPL) Review of SE Reports

New Products Subject of this Review	
Submission tracking numbers (STNs)	SE0021810, SE0023367-SE0023372, SE0023375-SE0023377, SE0023595
Common Attributes	
Submission date	September 8, 2020
Receipt date	September 8, 2020
Applicant	Soex India Pvt. LTD
Product manufacturer	Soex India Pvt. LTD
Application type	Regular Product Quantity
Product category	Waterpipe Tobacco Products
Product subcategory	Waterpipe Tobacco Filler
Cross-Referenced Submissions	
All STNs	None
Supporting FDA Memoranda Relied Upon in this Review	
All STNs	Addendum to Memorandum: Product quantity changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products (December 31, 2019)
Recommendation	
Issue Substantially Equivalent (SE) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Sharyn E. Miller -S
Date: 2021.09.28 07:46:36 -04'00'

Sharyn Miller, M.P.S.
Acting Branch Chief, Division of Regulatory Project Management
Office of Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Matthew R. Holman -S
Date: 2021.09.28 10:21:35 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

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1. BACKGROUND

1.1. NEW AND PREDICATE PRODUCTS

The applicant submitted information for the new and corresponding predicate products listed in detail in the Appendix.

1.2. REGULATORY ACTIVITY

On September 8, 2020, FDA received 11 Product Quantity Change SE Reports from Soex India Pvt. LTD. On November 18, 2020, FDA issued an Acceptance letter for SE0021810, SE0023367-SE0023372, SE0023375-SE0023377. On November 30, 2020, FDA issued an Acceptance letter for SE00023595.

1.3. SCOPE OF REVIEW

This review captures all compliance, regulatory, and scientific reviews completed for the new products that are the subject of this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1	
	Reviewer(s)	Review Date
Regulatory	Rida Tariq	9/27/2021
Environmental Science	Chad Baisden	7/21/2021

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate products are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews dated July 2, 2021, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate products are grandfathered and, therefore, are eligible predicate products.

OCE also completed a review to determine whether the new products are in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated July 29, 2021, concludes that the new products are in compliance with the FD&C Act.

3. SCIENTIFIC REVIEW

Full scientific review was not initiated by the Office of Science (OS) because the product characteristics of the new and corresponding predicate tobacco products are identical except for the following change in product quantity:

SE Report	New Product Quantity	Predicate Product Quantity	% Change
SE0021810, SE0023367, SE0023368, SE0023371, SE0023375, SE0023376	1000 grams (g)	250 g	↑300

SE Report	New Product Quantity	Predicate Product Quantity	% Change
SE0023369, SE0023370, SE0023372, SE0023377, SE0023595	1000 g	50 g	↑1900

OS prepared memoranda¹ summarizing its current thinking on product quantity changes. Existing data on product quantity changes are limited and do not address the size threshold (i.e., how much of a change in product quantity) necessary to raise different questions of public health. With respect to product quantity decreases, even though some of the currently available scientific evidence is specific to tobacco products, the studies do not separate out the effect of reduced price from size on consumption or initiation. Thus, based upon the currently available science and CTP's experience in reviewing SE Reports, product quantity changes do not cause new tobacco products to raise different questions of public health. Therefore, scientific review is unnecessary.

4. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on September 27, 2021. The FONSI was supported by an environmental assessment prepared by FDA on July 21, 2021.

5. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products are identical except for a change in product quantity from 250 g to 1000 g for SE0021810, SE0023367, SE0023368, SE0023371, SE0023375, and SE0023376, and 50 g to 1000 g for SE0023369, SE0023370, SE0023372, SE0023377, and SE0023595.

The OS memoranda¹ concludes that based on OS' experience and the currently available evidence, the difference in product quantity does not cause the new tobacco products to raise different questions of public health. I concur with this conclusion.

The predicate products meet statutory requirements because it was determined that they are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

The new products are currently in compliance with the FD&C Act. I concur with these reviews and recommend that SE order letters be issued.

FDA examined the environmental effects of finding these new products substantially equivalent and made a finding of no significant impact.

¹ See memorandum on product quantity changes, dated December 7, 2017, and addendum for deemed tobacco products, dated December 30, 2019.

6. APPENDICES

Appendix A. New and predicate products

Common Attributes of SE Reports		
Submission date	September 8, 2020	
Receipt date	September 8, 2020	
Applicant	Soex India Pvt. LTD.	
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 <small>Error! Bookmark not defined.</small>	Afzal Hookah Molasses Golden Amber 50g (Package) <small>Error! Bookmark not defined.</small>
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