

Technical Project Lead (TPL) Review of SE Reports

New Products Subject of this Review ¹	
STNs	SE0016688.PD1, SE0016868.PD1, SE0016964.PD1, SE0016996.PD1-SE0016999.PD1, SE0017241.PD1, SE0018021.PD1, and SE0018022.PD1
Common Attributes of SE Reports	
Submission date	June 15, 2020; ² July 17, 2020; ³ July 31, 2020; ⁴ August 3, 2020; ⁵ August 14, 2020; ⁶ and September 3, 2020 ⁷
Receipt date	June 15, 2020; ² July 17, 2020; ³ July 31, 2020; ⁴ August 3, 2020; ⁵ August 14, 2020; ⁶ and September 3, 2020 ⁷
Applicant	Philip Morris USA Inc.
Product manufacturer	Philip Morris USA Inc.
Application type	Regular
Product category	Cigarettes
Product subcategory	Combusted, Filtered
Cross-Referenced Submissions	
All STNs	(b) (4)
Supporting FDA Memoranda Relied Upon in this Review	
All STNs	None
Recommendation	
Issue Substantially Equivalent (SE) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

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Jeannie Jeong-Im, Ph.D.
Chemistry Branch Chief
Division of Product Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Todd L. Cecil -S Digitally signed by Todd L. Cecil -S
Date: 2022.09.19 11:50:52 -04'00'

Todd L. Cecil, Ph.D.
Acting Director
Office of Science

¹ Product details, amendments, and dates provided in the Appendix. SE means substantial equivalence (report). STN means submission tracking number.

² SE0016688.PD1

³ SE0016868.PD1

⁴ SE0016964.PD1

⁵ SE0016996.PD1-SE0016999.PD1

⁶ SE0017241.PD1

⁷ SE0018021.PD1 and SE0018022.PD1

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1. BACKGROUND

1.1. NEW AND PREDICATE PRODUCTS

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

1.2. REGULATORY ACTIVITY

See Appendix for products and amendments.

1.3. SCOPE OF REVIEW

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

Table 1. Disciplines reviewed

Discipline	Cycle 1	
	Reviewer(s)	Review Date
Regulatory	Rida Tariq ²	6/19/2020
	Dyamond Govan ³	7/24/2020
	Rida Tariq ⁴	8/6/2020
	Antonio Thornton ⁵	8/10/2020
	Rida Tariq ⁶	8/21/2020
	Pin Zhang ⁷	9/9/2020
Chemistry	Ethan Englund	8/16/2022
Engineering	Cao Chung	8/2/2022
Toxicology	Abhijit Ghosh	8/2/2022
Environmental Science	Thomas Creaven	7/21/2022

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review for SE0016688.PD1 to determine whether the applicant established that the predicate product is a grandfathered product (i.e., was commercially marketed in the United States as of February 15, 2007). The OCE review dated June 27, 2022, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate product is grandfathered and, therefore, is an eligible predicate product.

The predicate products in SE0016868.PD1, SE0016964.PD1, SE0016996.PD1-SE0016999.PD1, SE0017241.PD1, SE0018021.PD1, and SE0018022.PD1 were determined to be substantially equivalent by FDA under SE0015500, SE0015306, SE0015316, SE0015309, SE0015306, SE0015305, SE0014444, SE0015665, SE0015727, respectively. Therefore, the predicate products 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 August 10, 2022, concludes that the new products are in compliance with the FD&C Act.

3. SCIENTIFIC REVIEW

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

3.1. CHEMISTRY

The chemistry review concludes that the new products have different characteristics compared to the corresponding predicate products, but the differences do not cause the new products to raise different questions of public health from a chemistry perspective. All SE Reports list that the new products have identical or lower individual quantities of tobacco than the corresponding predicate product, except SE0016964.PD1 and SE0017241.PD1. (b) (4) increased by 15% in SE0016964.PD1, but all the other tobacco types decreased by 7% - 30%. SE0017241.PD1 has the addition of (b) (4), 40mg) and (b) (4) (b) mg (b) (4) and an addition of (b) mg of (b) (4) in the new product compared to the predicate product. However, (b) (4) decreased by 75% and (b) (4) decreased by 13%. SE0016688.PD1, SE0016964.PD1, and SE0017241.PD1 indicate added or higher (b) (4) in the tipping adhesive and added (b) (4), (b) (4) in the tipping paper in the new products. However, these amounts are small (0.1 mg) and not expected to affect smoke chemistry. The new products of SE0016868.PD1, SE0016964.PD1, SE0016996.PD1, SE0016997.PD1, SE0016998.PD1, SE0016999.PD1 and SE0017241.PD1 indicate higher (b) (4) (b) (4) that are balanced with lower (b) (4) and (b) (4) in the cigarette paper. Also, (b) (4) increased by 70% - 100% in the cigarette paper. There are also differences in the cigarette bands. (b) (4) was removed, and (b) (4) and (b) (4) were added to the new products. (b) (4) increased by 300% - 620%; however, the increase was only (b) (4) mg/cigarette in the new products. SE0016964.PD1, SE0016996.PD1 - SE0016999.PD1, and SE0017241.PD1 indicate that the new products have added (b) (4), and (b) (4) in the cigarette paper seam adhesive, while (b) (4) decreased 47% - 51%. The applicant provided the smoke yields of tar, nicotine, and carbon monoxide (TNCO), carbonyls (i.e., formaldehyde, acetaldehyde, acrolein, and crotonaldehyde), volatile organics (i.e., acrylonitrile, isoprene, benzene, 1,3-butadiene and toluene), ammonia, benzo[a]pyrene, N-nitrosonornicotine (NNN), and 4-[methyl(nitroso)amino]-1-(3-pyridinyl)-1-butanone (NNK) for the new and corresponding predicate products for SE0016868.PD1, SE0016964.PD1, SE0016996.PD1 - SE0016999.PD1, and SE0017241.PD1 under ISO and CI smoking regimens. They also provided appropriate method validation information. TOST⁸ analyses of HPHC data indicates that the HPHC data are statistically equivalent or non-equivalent but lower. Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new products to raise different questions of public health from a chemistry perspective.

3.2. ENGINEERING

The engineering review of SE0016688.PD1, SE0016868.PD1, SE0018021.PD1 and SE0018022.PD1 did not identify any differences in characteristics between the new and corresponding predicate products that could cause the new products to raise different questions of public health from an engineering perspective.

⁸ Two One-Sided T-test (TOST) is a statistical tool that calculates important analytical differences (IADs) using the Horwitz-Thompson equation.

The engineering review of SE0016964.PD1, SE0016996.PD1-SE0016999.PD1, and SE0017241.PD1 concludes that the new products have different characteristics compared to the corresponding predicate products, but the differences do not cause the new products to raise different questions of public health from an engineering perspective. The cigarette paper band width and band space target specifications have a 4.6% and a 1% difference respectively in the new products compared to the corresponding predicate products for SE0016964.PD1 and SE0016996.PD1 – SE0016999.PD1. Additionally, the target specification for cigarette paper band space is 1% higher in the new product compared to the predicate product for SE0016868.PD1. Moreover, the filter density and ventilation target specification and range limits show a 1% - 4% difference in the new products compared to the corresponding predicate for SE0016964.PD1 and SE0016996.PD1 – SE0016999.PD1. The differences in the cigarette paper band width, band space, filter density, and filter ventilation design parameters are anticipated to be too small to affect smoke chemistry, and therefore do not cause the new products to raise different questions of public health from an engineering perspective. For SE0016964.PD1, the tipping paper length target specification and range limits are 13% higher in the new product compared to the predicate product. The 13% increase in tipping paper length target specification and range limits may affect smoke constituent yields. Also, the target specification for tobacco filler mass of the new product is 7% lower compared to the predicate product. The difference in tobacco filler mass may affect smoke constituent yields; as a result. Lastly, the cigarette paper base paper porosity, filter pressure drop, and filter length have 23%, 8%, and 17% differences respectively between the new and corresponding predicate products. The differences in cigarette paper base paper porosity, filter pressure drop, and filter length may affect smoke constituents. Therefore, the evaluation of the yields of TNCO and tar, nicotine, and B[a]P for SE0016964.PD1 is deferred to chemistry. For SE0017241.PD1, the cigarette paper base paper porosity, cigarette paper band width, band space, and filter ventilation have 30%, 15%, 5%, and 7% differences respectively between the new and predicate products. The differences in cigarette paper base paper porosity, cigarette paper band width, band space, and filter ventilation may affect smoke constituents; as a result, the evaluation of TNCO and tar, nicotine, and B[a]P yields is deferred to chemistry. Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new products to raise different questions of public health from an engineering perspective.

3.3. TOXICOLOGY

The toxicology review concludes that the new products have different characteristics compared to the corresponding predicate products, but the differences do not cause the new products to raise different questions of public health from a toxicology perspective. In SE0016688.PD1, the new and predicate products are the same except for added ingredients to the tipping adhesive and tipping paper. These ingredient differences in the non-combusted components of the cigarette are not expected to be burned, volatilized, or to be a potential source of thermal degradation or pyrolysis resulting in the release of HPHCs for inhalation exposure. Therefore, the changes in the tipping components are not of toxicological concern. In SE0018021.PD1 and SE0018022.PD1, the tobacco rod is smaller in the new products compared to the corresponding predicate products, which resulted in lower levels of ingredients in the cigarette paper and tobacco filler. These differences do not raise concerns from a toxicology perspective. In SE0016868.PD1, ingredients were added or higher in the cigarette paper in the new product compared to the corresponding predicate product. In SE0016996.PD1 - SE0016999.PD1, ingredients were added or higher in the cigarette paper, seam adhesive, seam adhesive (b) (4), and tobacco additives in the new products compared to the corresponding predicate

products. In SE0016964.PD1 and SE0017241.PD1, ingredients were added or higher in the cigarette paper, seam adhesive, seam adhesive (b) (4), tobacco additives, and non-burned components in the new products compared to the corresponding predicate products. Ingredient differences in the non-combusted components in SE0016964.PD1 and SE0017241.PD1 are not expected to affect HPHC yields between the new and corresponding predicate products and are not of toxicological concern. The ingredient differences in the combusted portion of the cigarettes may affect HPHC yields in the new products compared to the corresponding predicate products. In SE0016868.PD1, SE0016964.PD1, SE0016996.PD1-SE0016999.PD1, and SE0017241.PD1, the applicant reported smoke yields generated by ISO and CI regimens for TNCO, acetaldehyde, acrolein, acrylonitrile, ammonia, benzene, benzo[a]pyrene, 1,3-butadiene, crotonaldehyde, formaldehyde, isoprene, NNK, NNN, and toluene. Chemistry has found these HPHC yields were analytically equivalent in the new products compared to the corresponding predicate products or analytically nonequivalent but lower. Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new products to raise different questions of public health from a toxicology perspective.

4. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on August 11, 2022. The FONSI was supported by an environmental assessment prepared by FDA on August 11, 2022.

5. CONCLUSION AND RECOMMENDATION

The new and the predicate products have the following characteristics:

SE0016868.PD1, SE0016964.PD1, SE0016996.PD1, SE0016997.PD1, SE0016998.PD1, SE0016999.PD1 and SE0017241.PD1

- Cigarette paper substrate:
 - (b) (4) ↓ 3-16%
 - (b) (4) ↑ (b) (4) mg)
 - (b) (4) ↑ (b) (4) mg)
 - (b) (4) ↓ (b) (4) mg)
 - (b) (4) ↓ (b) (4) mg)
 - (b) (4) ↑ 70%-100%
 - Bands:
 - (b) (4) : ↑ 300-620% (↑ (b) (4) mg)
 - (b) (4) : ↑ (b) (4) mg)
 - (b) (4) : ↑ (b) (4) mg)
 - (b) (4) : ↓ (b) (4) mg)

SE0016964.PD1, SE0016996.PD1, SE0016997.PD1, SE0016998.PD1, SE0016999.PD1, and SE0017241.PD1

- Cigarette paper seam adhesive:
 - (b) (4) ↑ (b) (4) mg)
 - (b) (4) ↑ (b) (4) mg)
 - (b) (4) ↓ 47-51%
 - (b) (4) ↑
- Cigarette paper band width (except for SE0017241.PD1): ↑ 4.6%

SE0016688.PD1, SE0016964.PD1 and SE0017241.PD1

- Tipping adhesive: Added or higher (b) (4) [REDACTED] ↑ 12% or ↑ (b) mg)
- Tipping paper: Added (b) (4), (b) (4) [REDACTED] ↑ (b) mg)

SE0016964.PD1

- Tobacco filler mass: ↓ 7%
- Cigarette paper base paper porosity: ↓ 23%
- Cigarette paper band width: ↑ 4.6%
- Filter density: ↓ 4%
- Filter pressure drop: ↑ 8%
- Filter length: ↑ 17%
- Tobacco:
 - (b) (4) : ↓ 7%
 - (b) (4) : ↑ 15%
 - (b) (4) : ↓ 30%
 - (b) (4) : RDL ↓ 11%
 - (b) (4) : ↓ 21%

Analytically nonequivalent but lower smoke constituents:

- tar ↓ 10% (ISO)
- crotonaldehyde ↓ 23% (ISO)
- tar ↓ 15% (CI)
- nicotine ↓ 14% (CI)
- ammonia ↓ 20% (CI)
- benzo[a]pyrene ↓ 18% (CI)

SE0017241.PD1

- Tipping lip release:
 - Lip release A:
 - (b) (4) [REDACTED] ↓ 29%
 - (b) (4) [REDACTED] ↓ 29%
 - Lip release B:
 - (b) (4) [REDACTED] ↑ (b) mg)
 - (b) (4) [REDACTED] ↑ (b) (4) mg)
- Cigarette paper base paper porosity: ↑ 30%
- Cigarette paper band width: ↓ 15%
- Cigarette paper band space: ↑ 5%
- Filter ventilation: ↓ 7%
- Tobacco:
 - (b) (4) : ↓ 6%
 - (b) (4) :
 - (b) : ↑ (b) mg)
 - (b) : ↓ 75%
 - (b) : ↑ (b) mg)
 - (b) (4) : ↓ 13%
 - (b) (4) : ↑ (b) mg)

Analytically nonequivalent, but lower smoke constituents:

- acrolein ↓15% (ISO)
- formaldehyde ↓25% (ISO)
- formaldehyde ↓31% (CI)

SE0018021.PD1 and SE0018022.PD1

- Cigarette length ↓1%
- Cigarette paper:
 - (b) (4) : ↓5% (SE0018021.PD1)
 - Band – (b) (4) : ↓5% (SE0018022.PD1)

I concur with the conclusions of all the scientific reviews that the applicant has demonstrated that these differences in characteristics do not cause the new products to raise different questions of public health as described in Section 3.1-3.3 above. There were minor differences in the new and predicate products of SE0016688.PD1, SE0018021.PD1, and SE0018022.PD1 such as a 0.1 mg/cigarette addition of (b) (4) (b) (4) in SE0016688.PD1 or a 1% decrease in cigarette length for SE0018021.PD1 and SE0018022.PD1. Due to the minor differences, these changes are not expected to appreciably impact TNCO or HPHC and no TNCO or HPHC information are needed for SE0016688.PD1, SE0018021.PD1, and SE0018022.PD1 at this time. However, there are differences in cigarette paper, cigarette paper bands, and seam adhesive between the new and predicate products of SE0016868.PD1, SE0016964.PD1, SE0016996.PD1 - SE0016999.PD1 and SE0017241.PD1. SE0016964 and SE0017241.PD1 also indicate differences in base paper porosity, band width, tobacco blend, and other design parameters. For SE0016868.PD1, SE0016964.PD1, SE0016996.PD1 - SE0016999.PD1, and SE0017241.PD1, the applicant reported smoke yields generated by ISO and CI regimens for TNCO, acetaldehyde, acrolein, acrylonitrile, ammonia, benzene, benzo[a]pyrene, 1,3-butadiene, crotonaldehyde, formaldehyde, isoprene, NNK, NNN, and toluene. Appropriate method validation information was provided. TOST evaluation of the smoke data indicates that the TNCO and HPHC data are statistically equivalent or non-equivalent and lower. Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new products to raise different questions of public health.

The predicate product of SE0016688.PD1 meets statutory requirements because it was determined that it is a grandfathered product (i.e., was commercially marketed in the United States as of February 15, 2007).

The predicate products of SE0016868.PD1, SE0016964.PD1, SE0016996.PD1-SE0016999.PD1, SE0017241.PD1, SE0018021.PD1, and SE0018022.PD1 were previously determined to be substantially equivalent by FDA, as identified on the cover page of this review. Where an applicant supports a showing of SE by comparing the new product to a product that FDA previously found SE, in order to issue an SE order, FDA must find that the new product is substantially equivalent to a product commercially marketed in the United States as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act). No differences in characteristics between the new product and the product commercially marketed in the United States as of February 15, 2007, raise different questions of public health.

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.

6. APPENDICES

Appendix A. New and predicate products^{a,b}

Common Attributes of SE Reports		
Submission date	June 15, 2020; ² July 17, 2020; ³ July 31, 2020; ⁴ August 3, 2020; ⁵ August 14, 2020; ⁶ and September 3, 2020 ⁷	
Receipt date	June 15, 2020; ² July 17, 2020; ³ July 31, 2020; ⁴ August 3, 2020; ⁵ August 14, 2020; ⁶ and September 3, 2020 ⁷	
Applicant	Philip Morris USA Inc.	
Product manufacturer	Philip Morris USA Inc.	
Product category	Cigarettes	
Product subcategory	Combusted, Filtered	
Attributes	New Product	Predicate Product
STN	SE0016688.PD1	GF1200269
Product name	Marlboro Blend No. 27 100's Box	Chesterfield 100's Lights Box
Eligibility status	Not applicable (N/A)	Grandfathered
Package type	Hard Pack	Hard Pack
Package quantity	20 cigarettes	20 cigarettes
Characterizing flavor	None	None
Length	98.5 millimeters (mm)	98.5 mm
Diameter	7.89 mm	7.89 mm
Ventilation	28%	28%
Nicotine Source	Tobacco	Tobacco
STN	SE0016868.PD1	SE0015500
Product name	L&M Turkish Blend Box	L&M Turkish Blend Box
Eligibility status	N/A	Previously Found SE
Package type	Hard Pack	Hard Pack
Package quantity	20 cigarettes	20 cigarettes
Characterizing flavor	None	None
Length	83 mm	83 mm
Diameter	7.89 mm	7.89 mm
Ventilation	23%	23%
Nicotine Source	Tobacco	Tobacco
STN	SE0016964.PD1	SE0015306
Product name	Marlboro Menthol Smooth 100's Box	Marlboro Menthol Black Special Blend 100's Box
Eligibility status	N/A	Previously Found SE
Package type	Hard Pack	Hard Pack
Package quantity	20 cigarettes	20 cigarettes
Characterizing flavor	Menthol	Menthol

^a Brand/sub-brand or other commercial name used in commercial distribution

^b Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. As such, nicotine source is considered a required property for unique identification.

<https://www.congress.gov/bill/117th-congress/house-bill/2471>

Attributes	New Product	Predicate Product
Length	98.5 mm	98.0 mm
Diameter	7.89 mm	7.89 mm
Ventilation	15%	16%
Nicotine Source	Tobacco	Tobacco
Additional Property	N/A	Tipping Paper 2
STN	SE0016996.PD1	SE0015316
Product name	Marlboro Edge Box	Marlboro Edge Box
Eligibility status	N/A	Previously Found SE
Package type	Hard Pack	Hard Pack
Package quantity	20 cigarettes	20 cigarettes
Characterizing flavor	None	None
Length	83 mm	83 mm
Diameter	7.89 mm	7.89 mm
Ventilation	17%	17%
Nicotine Source	Tobacco	Tobacco
STN	SE0016997.PD1	SE0015309
Product name	Marlboro Menthol 100's Box	Marlboro Menthol Black Special Blend 100's Box
Eligibility status	N/A	Previously Found SE
Package type	Hard Pack	Hard Pack
Package quantity	20 cigarettes	20 cigarettes
Characterizing flavor	Menthol	Menthol
Length	98 mm	98 mm
Diameter	7.89 mm	7.89 mm
Ventilation	18%	16%
Nicotine Source	Tobacco	Tobacco
Additional property	Tipping Paper 1	Tipping Paper 1
STN	SE0016998.PD1	SE0015306
Product name	Marlboro Menthol 100's Box	Marlboro Menthol Black Special Blend 100's Box
Eligibility status	N/A	Previously Found SE
Package type	Hard Pack	Hard Pack
Package quantity	20 cigarettes	20 cigarettes
Characterizing flavor	Menthol	Menthol
Length	98 mm	98 mm
Diameter	7.89 mm	7.89 mm
Ventilation	18%	16%
Nicotine Source	Tobacco	Tobacco
Additional property	Tipping Paper 2	Tipping Paper 2
STN	SE0016999.PD1	SE0015305
Product name	Marlboro Menthol 100's Box	Marlboro Menthol Black Special Blend 100's Box
Eligibility status	N/A	Previously Found SE
Package type	Hard Pack	Hard Pack
Package quantity	20 cigarettes	20 cigarettes

Attributes	New Product	Predicate Product
Characterizing flavor	Menthol	Menthol
Length	98 mm	98 mm
Diameter	7.89 mm	7.89 mm
Ventilation	18%	16%
Nicotine Source	Tobacco	Tobacco
Additional property	Tipping Paper 3	Tipping Paper 3
STN	SE0017241.PD1	SE0014444
Product name	Marlboro Menthol Special Blend 100's Box	Marlboro Menthol Gold Pack 100's Box
Eligibility status	N/A	Previously Found SE
Package type	Hard Pack	Hard Pack
Package quantity	20 cigarettes	20 cigarettes
Characterizing flavor	Menthol	Menthol
Length	98.5 mm	98.5 mm
Diameter	7.89 mm	7.89 mm
Ventilation	26%	33%
Nicotine Source	Tobacco	Tobacco
STN	SE0018021.PD1	SE0015665
Product name	Marlboro Special Select (Gold Pack) Box	Marlboro Special Select (Gold Pack) Box
Eligibility status	N/A	Previously Found SE
Package type	Hard Pack	Hard Pack
Package quantity	20 cigarettes	20 cigarettes
Characterizing flavor	None	None
Length	83 mm	84 mm
Diameter	7.89 mm	7.89 mm
Ventilation	23%	23%
Nicotine Source	Tobacco	Tobacco
STN	SE0018022.PD1	SE0015727
Product name	Chesterfield Menthol 100's Box	Chesterfield Menthol 100's Box
Eligibility status	N/A	Previously Found SE
Package type	Hard Pack	Hard Pack
Package quantity	20 cigarettes	20 cigarettes
Characterizing flavor	Menthol	Menthol
Length	98 mm	99 mm
Diameter	7.89 mm	7.89 mm
Ventilation	None	None
Nicotine Source	Tobacco	Tobacco

Appendix B. Amendments

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Brief Description
8/26/2020	8/26/2020	SE0017607	SE0016996.PD1	Yes	Correction or clarification to provide the current Industrial User Permit intended for the environmental assessment.
8/26/2020	8/26/2020	SE0017608	SE0016997.PD1-SE0016999.PD1	Yes	Correction or clarification to provide the current Industrial User Permit intended for the environmental assessment.