

Each specific request ("Additional Clarifying Question") included in the Request Letter is reproduced below in bold type followed by Swedish Match's response.

Additional Clarifying Question 1. All of your portioned PMTAs/MRTPAs provide air permeability test data for the non-woven pouch material in the new products. However, you do not include pouch paper air permeability target specification and range limits needed to fully characterize the products. Pouch paper air permeability is inherent to the material of the pouch and is a major factor in nicotine release. Therefore, the pouch paper must have defined air permeability specifications. You need to demonstrate target specifications are implemented and adhered to during manufacturing. For PM0000011-PM0000017 and MR0000021-MR0000029, provide the target specification and upper and lower range limits for pouch paper air permeability (L/m²/s).

Swedish Match response to Additional Clarifying Question 1 for PM0000011-PM0000017 and MR0000021- MR0000029:

The target specification and upper and lower range limits for pouch paper air permeability is (b) (4) L/m²/s. The pouch material supplier's declaration of authenticity (DOA) has been updated to include the target specification and upper and lower range limits for pouch paper air permeability. See **Attachment B-20150629**. Air permeability data and specification from the supplier's DOA are reproduced in Table 1-1 below.

Table 1-1. Air Permeability

	2014	Specification	
Air permeability strength	(b) (4)	Target	(b) (4)
Min	(b) (4)	Minimum	(b) (4)
Max	(b) (4)	Maximum	(b) (4)
N	(b) (4)		
St.dev	(b) (4)		

Additional Clarifying Question 2. All of your portioned PMTAs/MRTPAs include certificates of analysis for pouch paper air permeability and heat sealability. The COAs do not contain sufficient information to evaluate the data. The certificates of analysis provide the parameter units and test data values. In order to fully evaluate whether or not the target specifications are met, provide certificates of analysis with the target specification and quantitative acceptance criteria as indicated by the supplier for pouch paper air permeability and heat sealability.

Swedish Match response to Additional Clarifying Question 2 for PM0000011-PM0000017 and MR0000021- MR0000029:

Air permeability

A declaration of authenticity (DOA) from the pouch material supplier which included performance criteria values, parameter units, test data average value, and the standard deviation of the test data as well as the minimum and maximum values of the test data for air permeability were provided in Attachment N-

20140909, pages 207, 222, 239, 256, 274, 291, 308, 325, and 343, of Swedish Match's November 6, 2014, response to the September 9, 2014 Advice/Information Request for SE0010525 through SE0010533.

The target specification and quantitative acceptance criteria as indicated by the supplier were not included on the DOA. Swedish Match is providing the suppliers updated DOA which includes the suppliers target specification and quantitative acceptance criteria for air permeability in Attachment B-20150629. Air permeability data and specification from the supplier's DOA are reproduced in Table 1-1 above

Heat Sealability

A declaration of authenticity (DOA) from the pouch material supplier which included performance criteria values, parameter units, test data average value, and the standard deviation of the test data as well as the minimum and maximum values of the test data for heat sealability were provided in:

- ATTACHMENT Q3b1-20150605, page 29 of 32, of Swedish Match's June 23, 2015 response to the June 12, 2015 Advice/Information Request, and
- ATTACHMENT Q3b1-20150605, page 30 of 33, of Swedish Match's June 19, 2015 response to the June 5, 2015 Advice/Information Request.

The target specification and quantitative acceptance criteria as indicated by the supplier were not included on the DOA. The material supplier's heat sealability target specification of (b) (4) with a tolerance above or equal to (b) (4) was included in Swedish Match's June 19, 2015 (lines 427-428) and June 23, 2015 (lines 426-427) responses to Advice/Information Requests of June 5, 2015 and June 12, 2015, respectively.

To further aid FDA, Swedish Match is providing the suppliers updated DOA which includes the suppliers target specification and quantitative acceptance criteria for heat sealability in Attachment C-20150629. Heat sealability data and specification from the supplier's DOA are reproduced in Table 2-1 below.

Table 2-1. Heat Sealability

	2014	Specification	
Average heat seal strength	(b) (4)	Target	(b) (4)
Min		Tolerance	
Max			
N			
St.dev			

On Jun 29, 2015, at 11:01 AM, Brown, Asia <Asia.Brown@fda.hhs.gov> wrote:

Good Morning Mr. Roerty,

Are you available at 2 pm today, June 29, 2015 for a 30 minute teleconference with our Engineer to discuss the following information below for your PMT Applications PM0000011-PM0000017 and MRTP Applications MR0000021-MR0000029?

1. All of your portioned PMTAs/MRTPAs provide air permeability test data for the non-woven pouch material in the new products. However, you do not include pouch paper air permeability target specification and range limits needed to fully characterize the products. Pouch paper air permeability is inherent to the material of the pouch and is a major factor in nicotine release. Therefore, the pouch paper must have defined air permeability specifications. You need to demonstrate target specifications are implemented and adhered to during manufacturing. For PM0000011-PM0000017 and MR0000021-MR0000029, provide the target specification and upper and lower range limits for pouch paper air permeability (L/m²/s).
2. All of your portioned PMTAs/MRTPAs include certificates of analysis for pouch paper air permeability and heat sealability. The COAs do not contain sufficient information to evaluate the data. The certificates of analysis provide the parameter units and test data values. In order to fully evaluate whether or not the target specifications are met, provide certificates of analysis with the target specification and quantitative acceptance criteria as indicated by the supplier for pouch paper air permeability and heat sealability.

Please feel free to contact me with any questions.

Regards,
Asia

Asia Brown

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(b) (4)

