June 23, 2015

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FOOD AND DRUG ADMINISTRATION
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SUBJECT: RESPONSE TO ADVICE/INFORMATION REQUEST for PM0000010–PM0000017

Dear Sir or Madam:

Swedish Match North America, Inc. ("Swedish Match" or "we") writes in response to FDA's Advice/Information Request dated June 12, 2015 (the "Request Letter"), included below as **Attachment A**, regarding our Premarket Tobacco Applications ("PMTAs") received by FDA March 11, 2015 for the following eight (8) products (collectively, the "PM Reports"):

- PM0000010, General Loose
- PM0000011, General Dry Mint Portion Original Mini
- PM0000012, General Portion Original Large
- PM0000013, General Classic Blend Portion White Large – 12 ct
- PM0000014, General Mint Portion White Large
- PM0000015, General Nordic Mint Portion White Large – 12 ct
- PM0000016, General Portion White Large
- PM0000017, General Wintergreen Portion White Large

We set forth below our response to each Agency request enumerated in the Request Letter. This response and its associated references and attachments have been constructed as directed by FDA in the Request Letter. Where appropriate, we have included any previously submitted information as well as direct FDA to the sections(s), page(s), and line number(s) of our prior MRTPAs and SE Reports, including amendments, where this information can also be found. For FDAs aid, following is a list of corresponding MR and SE numbers related to PM numbers.

PM STN	New Product Name	SE STN	MR STN
PM0000010	General Loose 1.59 oz. (45g)	SE0010524	MR0000020
PM0000011	General Dry Mint Portion Original Mini 0.21 oz. (6g)	SE0010525	MR0000021
PM0000012	General Portion Original Large 0.9 oz. (24g)	SE0010526	MR0000022
PM0000013	General Classic Blend Portion White Large 0.38 oz. (10.8g)	SE0010528	MR0000024
PM0000014	General Mint Portion White Large 0.9 oz. (24g)	SE0010529	MR0000025
PM0000015	General Nordic Mint Portion White Large .38 oz. (10.8g)	SE0010531	MR0000027
PM0000016	General Portion White Large 0.9 oz. (24g)	SE0010532	MR0000028
PM0000017	General Wintergreen Portion White Large 0.9 oz. (24g)	SE0010533	MR0000029

Swedish Match submits that this response and the information we are supplying in connection with this response are trade secret, proprietary information that is protected under state and federal law from public disclosure. This information should therefore be handled in accordance with the security procedures adopted by FDA in connection with enforcement of the FDCA.

We appreciate your consideration of this Response and amendments to our PMTAs identified above. If further information is required, please contact us.

Sincerely yours,

(b) (6)

Gerard J. Roerty, Jr.
Vice President, General Counsel & Secretary

Document Tables:

Table 3a-1. Revised summary can weight data for PM-14.
Table 5a-1. Snus blend prior to packaging upper tolerance limits for moisture and pH.
Table 5a-2. Finished packaged product upper tolerance limits for moisture and pH.
Table 5d-1. PM-16 and PM-17 SM (b) (4) data.
Table 5d-2. PM-14 Aw data from shelf life study.

Document Attachments:

Attachment A – Request Letter dated 6/12/2015
Attachment Q2a1-20150605 – (b) Protocol 09g Pouches
Attachment Q3a1-20150612 – Can Weight Data for PM-14
Attachment Q3b1-20150605 – (b) (4)
Attachment Q3b2-20150605 – (b) (4) Procedure
Attachment Q5b1-20150605 – Aw data US Products

Each request for additional information or clarification ("Additional Clarifying Question") identified in the Request Letter is reproduced below in bold type followed by Swedish Match's response for each identified PM Report.

Additional Clarifying Question 1. All of your portioned PMTAs provide information on the design parameters for the new products. However, you do not include pouch paper porosity and wicking, which are needed to fully characterize the products. Pouch paper porosity and wicking are inherent to the material of the pouch and are major factors in nicotine release. Once the pouch is placed in the user's mouth, the porosity and wicking of the pouch control the amount and rate of nicotine absorption. Therefore, the pouch paper must have defined porosity and wicking specifications or another comparable specification. Demonstrate that target specifications are implemented and adhered to during manufacturing. For PM0000011-PM0000017, provide the target specification and upper and tower range limits for pouch paper porosity (CU) and pouch paper wicking or another comparable specification.

Additionally, confirm the target specifications are met by providing the test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance (pass/fail) criteria, data sets, and a summary of the results for pouch paper porosity (CU) and pouch paper wicking or another comparable specification for PM0000011-PM0000017. Certificates of analysis from the material supplier may satisfy this deficiency. If you choose to address this part by providing certificates of analysis for the parameters listed above, the certificates of analysis must include a target specification; quantitative acceptance criteria; parameter units; test data average value; and either the standard deviation of the test data or the minimum and maximum values of the test data.

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

FDA states in the question that, "Once the pouch is placed in the user's mouth, the porosity and wicking of the pouch control the amount and rate of nicotine absorption." Our research[1] does not indicate this is the case. (b) (4)
(b) (4)

(b) (4)

[1] (b) (4)
(b) (4) .

Further, nicotine uptake or uptake of HPHCs from the pouches due to the pouch material or slight variation in the physical shape of the pouch would be dwarfed by the large inter-individual variations we see in extractions which are more likely related to bodily processes, saliva production, etc. which varies between individuals.

It was not Swedish Match's intent to infer that pouch paper regulated or buffered nicotine extraction or that we have any pouch paper design features that could be interpreted as parameters to measure and or maintain the consistency in the release of nicotine when we made the following statement about pouch paper, "From a consumer perspective, it is important that the pouch material (which is used in the portion snus products) is soft and has texture properties which facilitate the release of nicotine and flavor compounds" in the MRTPA page 147, sections 3.1.5.

(b) (4)

(b) (4)

Notwithstanding, Swedish Match has previously provided comments and or information regarding pouch paper porosity and pouch paper wicking as indicated below. Where applicable we refer FDA to prior amendments submitted for MR0000021-MR0000029 and SE0010525-SE0010533.

Pouch paper porosity

Comparable information for porosity has been supplied in the form of air permeability information.

We refer FDA to;

1. Swedish Match's December 3, 2014, responses to the November 12, 2014 Advice/Information Request, where on page 44 of 54 we stated;

"The requested subcomponent information, as well as basis weight per unit of use, fabric weight (basis weight), fabric width, pouch paper thickness, and air permeability, for each product can be found in our Response to Scientific Advice/Information Request for SE0010524-SE0010533 dated November 6, 2014, Attachment F-20140909 for each SE0010524-SE0010533, pages 112-137 of 731 (see table 21-1 below)."

2. Swedish Match's March 6, 2015, responses to the February 5, 2015 RESPONSE TO PRELIMINARY FINDING for SE0010524-SE0010533, where on page 6 we stated;

"The information in Attachment M-20140909 from the Swedish Match response to Scientific Advice/Information Request, Deficiency 1 from 6th of November 2014 is correct. The Amendment narrative, line 786-789, page 23 of 731, explains that there is no specification for porosity (air permeability). The supplier provided a Declaration of Authenticity (DOA) containing raw data information found in Attachment N-20140909 from our response to Scientific Advice/Information Request, dated 9th of September 2014. Swedish Match regrets that we inadvertently inserted the DOA data into attachment F-20140909.

Attachment F-20140909 has been corrected to indicate there is no specification for porosity/air permeability. The corrected attachment F-20140909 is called "Attachment F-20150205". The corrected information has been highlighted on the attachment."

3. Swedish Match's November 6, 2014, responses to the September 9, 2014 Advice/Information Request, for SE0010524-SE0010533 (MR0000020 – MR0000029)

    a. Page 23, line 786-791 we stated
        i. "It has not been our practice to measure or monitor pouch paper porosity. In our opinion, this is not a design feature, and, as such, we have set no specifications. According to the pouch paper vendor for Swedish Match, no current GMP exists for the measurement of porosity/permeability of the material. Furthermore, no standard test method exists for these materials. To aid CTP in their evaluation, we are including in Table D1-2 below the pouch paper air permeability and density data provided by the vendor."

    b. Page 24 lines 795-796, Table D1-2. Supplier pouch paper air permeability and density data.

    c. Page 28, line 928-930 for SE0010525, i.e., MR0000021, we stated
        i. "summary of test data for air permeability for the new product was provided by the supplier. See attachment, Attachment M-20140909. The supplier provided no test data for the grandfathered product."

    d. Page 29 line 976-979 for SE0010526 - SE0010533, i.e., MR0000022-MR0000029
        i. Same statement as c(i) above

    e. Summary data for
        i. PM0000011 see page 184 of 731 ATTACHMENT M-20140909 (SE0010525) (Page 1 of 1) item 7
        ii. PM0000012 see page 185 of 731 ATTACHMENT M-20140909 (SE0010526) (Page 1 of 1) item 7
        iii. PM0000013 see page 187 of 731 ATTACHMENT M-20140909 (SE0010528) (Page 1 of 1) item 7
        iv. PM0000014 see page 188 of 731 ATTACHMENT M-20140909 (SE0010529) (Page 1 of 1) item 7
        v. PM0000015 see page 190 of 731ATTACHMENT M-20140909 (SE0010531) (Page 1 of 1) item 7
        vi. PM0000016 see page 191 of 731ATTACHMENT M-20140909 (SE0010532) (Page 1 of 1) item 7
        vii. PM0000017 see page 192 of 731 ATTACHMENT M-20140909 (SE0010533) (Page 1 of 1) item 7

f. Test data/data sets; the supplier's certificate (declaration of authenticity (DOA)) can be found as follows. The DOA is identical for each product
    i. PM0000011, ATTACHMENT N-20140909 (SE0010525) Page 207 of 731
    ii. PM0000012, ATTACHMENT N-20140909 (SE0010526) Page 222 of 731
    iii. PM0000013, ATTACHMENT N-20140909 (SE0010528) Page 256 of 731
    iv. PM0000014, ATTACHMENT N-20140909 (SE0010529) Page 274 of 731
    v. PM0000015, ATTACHMENT N-20140909 (SE0010531) Page 308 of 731
    vi. PM0000016, ATTACHMENT N-20140909 (SE0010532) Page 325 of 731
    vii. PM0000017, ATTACHMENT N-20140909 (SE0010533) Page 343 of 731

g. Test protocol information
    i. ATTACHMENT O-20140909 Page 354 of 731

<u>Pouch paper wicking</u>

Swedish Match does not have any specifications, test data, or data sets for wicking or anything comparable to wicking. The material as offered to us by the supplier has never had a specification for wicking. Consequently, Swedish Match has never developed a specification for wicking or explored the development of method or test protocols. As it pertains to the nonwoven material used by Swedish Match, we have no knowledge of a standard or validated method for the measurement of wicking.

(b) (4)

(b) (4)

We refer FDA to like statements made in previous amendments;

1. Swedish Match's May 22, 2015, responses to the April 28, 2015 Advice/Information Request
    a. Page 24 of 470 we stated;
        i. (b) (4)
    b. Page 466 of 470 we stated;
        i. (b) (4)

(b) (4)

(b) (4)

Additional Clarifying Question 2. All of your PMTAs provide the performance criteria and design parameter test data. However, you do not include all of the information needed to fully characterize the new products. In order to adequately characterize the new products, it is necessary to evaluate the testing procedures. You stated that you submitted the protocol for pouch weight (portion mass) measurements for PM0000013-PM0000017; however, no protocol was found in the June 3,2015 amendment. Additionally, you do not provide test protocols for portion length, width, and thickness for PM0000011-PM0000017. Provide the protocol documents for measuring the following design parameters:

a. Pouch weight (portion mass) for PM0000013-PM0000017

b. Portion length, width, and thickness for PM0000011-PM0000017

Swedish Match response to Additional Clarifying Question 2.a. for PM0000013-PM0000017:

PM0000013 and PM0000015

PM0000013 and PM0000015 are 0.9g white portions which are randomly packaged in a can. Swedish Match utilizes (b) (4) . (b) (4) (b) (4) (b) (4) (b) (4) .

The specification for a single pouch is (b) (4) The specification for a "sample" (2 pouches) is (b) (4) g (b) (4) (b) (4) (b) (4) as noted in the attached (b) (4) chart. (**See Attachment Q2a1-20150605.)**

(b) (4) (b) (4)

PM0000014, PM0000016, and PM0000017

PM0000014, PM0000016, and PM0000017 are 1.0g white portions which are packaged in a star formation in a can. The packing technique (star formation) and the in-line weight check of the finished can are used to control the pouch weight.

The packing technique is (b) (4)) (b) (4) (b) (4) .

Weight of finished cans is monitored by an in-line check-weigher. (b) (4) (b) (4) (b) (4) (b) (4) . (b) (4) . The lower and upper pouch weight limits are controlled by the pouch packing machine. Thus, the pouch weight design feature is (b) (4) (b) (4)

Swedish Match response to Additional Clarifying Question 2.b. for PM0000011-PM0000017:

Swedish Match does not have test protocols for pouch length, width, and thickness. We do not perform routine quality checks for the purpose of monitoring or controlling pouch length, width, and thickness. We rely on pouch weight, pouch material width, and equipment settings/design to control pouch dimensions.

When off-line measurements are made to describe these dimensions, simple (un-calibrated/non-standardized) tools such as rulers for width and length and calipers for thickness are used. Swedish Match does not have a standardized or validated test protocol for the measurement of these dimensions and does not consider these dimensions to be release criteria due to the fixed nature of the processing equipment and materials.

PM0000011-PM0000012

PM0000011 and PM0000012 are pouch products that are formed on what is known as a (b) (4)

Width; (b) (4) (b) (4) (b) (4) (b) (4) . Swedish Match reasonably does not monitor this fixed condition or consider it to be a release criterion.

Length; (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) . Swedish Match reasonably does not monitor this fixed condition or consider it to be a release criterion.

(b) (4) Thickness; the [redacted],
(b) (4) [redacted]
(b) (4) [redacted].

PM0000013 and PM0000015

PM0000013 and PM0000015 are 0.9g white portions which are randomly packaged in a can. (b) (4) [redacted]
(b) (4) [redacted]

(b) (4) [redacted]
(b) (4) [redacted] described below.

(b) (4) [redacted]:

1. (b) (4) [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. (b) (4) [redacted]
6. [redacted]
   a. (b) (4) [redacted]

(b) (4)

(b) (4)

7. (b) (4)

Thickness; (b) (4)

(b) (4)

(b) (4) .

PM0000014, PM0000016-PM0000017

PM0000014, PM0000016, and PM0000017 are 1.0g white portions which are packaged in a star formation in a can. (b) (4) .

(b) (4)

Step 7 above is replaced by the following process to accomplish (b) (4)

(b) (4) . Further

(b) (4) process design described below.

(b) (4) ;

(b) (4)

Thickness; (b) (4)

(b) (4)

(b) (4) .

Additional Clarifying Question 3. All of your PMTAs include information confirming that the quality control tests are executed and some of the performance criteria are met. However, clarification is required for some of the performance criteria. Provide the following information:

a. **In PM0000010-PM0000012 and PM0000014 the can weights are outside the performance criteria range limits. Since performance criteria are the pre-specified limits to establish product-to-product consistency, the resulting test data must conform to the limits to ensure quality control among the products is regulated. It is unclear why the can weights are out of specification. Therefore, provide a justification for these discrepancies.**

b. **In PM0000013-PM0000017, you do not provide test data for (b) (4), stating that a specification does not exist for this parameter. However, in the original submission, you provided a performance tolerance value for (b) (4) of (b) (4) in Table 3-39. If there is a tolerance value for this quality control parameter, then corresponding test data should exist. Provide (b) (4) quality control test data (i.e., measured values of quality control tests), including data sets and a summary of the results for PM0000013-PM0000017. Certificates of analysis from the material supplier may satisfy this deficiency. If you choose to address this deficiency by providing certificates of analysis for any of the parameters listed above, the certificates of analysis must include performance criteria values; parameter units; test data average value; and either the standard deviation of the test data or the minimum and maximum values of the teat data. If you do not have specifications for (b) (4), explain why you included performance tolerance value for (b) (4) of (b) in the original submission.**

Swedish Match response to Additional Clarifying Question 3.a. for PM0000013-PM0000017:

Test data for can weights were presented in the Attachment Q4e1-20150428 of Swedish Match's May 22, 2015 response to the April 28, 2015 Advice/Information Request, Additional Clarifying Question 4.e.

PM0000010-PM0000011, PM0000013, and PM0000015 (MR0000020-MR0000021, MR0000024, and MR0000027, respectively, in Attachment Q4e1-20150428)

Test data outside of the performance criteria range limits were the result of where the samples were collected in the process. The test data presented in Attachment Q4e1-20150428 was obtained from quality audit information and not from the in-line check-weigher as check-weigher data is not retained. After further review, we recognized the quality audit samples were collected (b) (4) (b) (4)

PM0000012

PM0000012 did not have can weight test data outside the performance criteria range limits of (b) (4) g ((b) (4) g - (b) (4) g). Range for data presented was (b) (4) to (b) (4) grams.

PM0000014

All test data outside of the range limits occurred for the manufacturing date (b) (4) . The test data for this date is not representative of manufacturing capability for this product (b) (4) - (b) (4) . We regret the inclusion of this data and ask that data for the November 19, 2012 date be discarded. A revised data set including data from 2015 and removing data from November 19, 2012 is provided in **Attachment Q3a1-20150612**.

Further, the summary data for PM0000014 is revised in table 3a-1 to reflect the removal of the November 19, 2012 data and inclusion of data from 2015.

Table 3a-1. Revised summary can weight data for PM0000014.

CAN WEIGHT (g)	4352 PM0000014
Target (Lower Tolerance - Upper Tolerance)	(b) (4)
Count	
Average	
Standard Deviation	

Swedish Match response to Additional Clarifying Question 3.b. for PM0000011-PM0000017:

Swedish Match is providing a declaration of authenticity (DOA) from the material supplier in **Attachment Q3b1-20150605** which includes 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. The DOA data indicates the performance tolerance value for (b) (4) of (b) (4), as indicated in Table 3-39 of the original MRTPA submission, is met.

The material supplier's (b) (4) target specification is (b) (4) g with a tolerance above or equal to (b) (4) g. The method for this is the supplier's own method named (b) (4) **(see Attachment Q3b2-20150605)**.

Additional Clarifying Question 4. All of your PMTAs include design parameter test data, confirming that the target specifications are met. However, the test data for the portion dimensions are inconsistent. Some of the test data for portion length, width, and thickness falls within the range limits for the new products, but some of the data does not fall within the range limits. You recognize that some of the test data is outside of the specification range limits, stating that the portion dimensions are not release criteria and in turn, the test data is acceptable. However, range limits are used to characterize the product based on the target specifications and product attributes (e.g., taste, use, and HPHC limits). Test data demonstrate if the product conforms to the standards. When manufacturing data does not fall

within the range limits of the specification, it is an indication that deviations are occurring (e.g., raw materials are out of specification, equipment malfunction). Regardless of whether the parameter is a release criterion, the test data should be representative of the range limits. Provide a justification for these discrepancies.

Swedish Match response to Additional Clarifying Question 4 for PM0000013-PM0000017:

(b) (4)

(b) (4)

None of the out of range test data deviates more than (b)(mm. It is reasonable to assume, given the rudimentary measurement methods employed, that inconsistent measurement practices and subjective human examination are the primary contributing factor to data test results that were recorded as out of range and not that deviations are occurring in the manufacturing process.

Most consistently there was out of range data for the thickness. This is not surprising. Depending how the pouch was handled during the measurement a number of results are possible. Snus could have been unevenly disturbed in the pouch and depending on whether or not the pouch was flattened or fluffed up, for example, the thickness measurement would certainly be effected.

Likewise length measurements are subject to the effects of sample handling. Depending on the amount of pressure exerted on the pouch or whether or not it was fully straitened a number of results are possible.

With the exception of a single data point on PM0000014, all of the width data points were within specification. This demonstrates that reliance on fixed material and equipment settings is sufficient to control the width of the products and the one outlier is most likely due to test method.

Additional Clarifying Question 5. **All of your PMTAs report that your company employs an automatic control system for approval of snus blends before the blend is released for packaging. This automatic control system assesses the values of moisture content, pH, a_w, and sensory characteristics. The analytical values are compared with the specifications, and snus blends having analytical values within the specified tolerance limits are immediately approved.** (b) (4) (b) (4) (b) (4) (b) (4) **. However, the specifications provided in your PMTAs do not include upper tolerance limits for moisture or pH for the new products in PM0000011 and PM0000012. Furthermore, during FDA inspection of your manufacturing and testing facilities on April 13-17, 2015, it was discovered that QEMS instruction titled "**(b) (4) (b) (4) **" for handling the out-of-specification situations seems to be inconsistent with the procedure described in your PMTAs. The instructions In this QEMS indicate that in** (b) (4) (b) (4) **Therefore, the following information is needed:**

a. **Upper tolerance limits for moisture and pH for the new products in PM0000011 and PM0000012.**

b. **Measured values for a_w for all new products.**

c. **Specifications for the** (b) (4) (b) (4) (b) (4)

d. **Information and data to support that the** (b) (4) **specifications ensure the same stability profile as the** (b) (4) **(i** (b) (4) (b) (4) (b) (4) **).**

Swedish Match response to Additional Clarifying Question 5.a. for PM0000011-PM0000012:

The May 22, 2015 response to April 28, 2015 Advice/Information Request, page 45, response to additional clarifying question 3.e., referred CTP to our December 3, 2014 response to November 12, 2014 Advice/Information Request, additional clarifying question 9, at page 21 in "Table 9-1, with the updated Table 3-37(20141112)" for product General Dry Mint Portion Original Mini (SKU 4800, PM0000011/ MR0000021) and General Portion Original Large (SKU 4880, PM0000012/MR0000022). To aid CTP, the upper tolerance limits for moisture and pH for PM0000011 and PM0000012 snus blends before the blend is released for packaging can be found below in Table 5a-1.

Table 5a-1. Snus blend prior to packaging upper tolerance limits for moisture and pH.

	General Dry Mint Portion Original Mini (SKU 4800, PM0000011)	General Portion Original Large (SKU 4880, PM0000012)
Upper tolerance limit for moisture	(b) (4)	
Upper tolerance limit for pH		

If the information FDA is seeking clarity for is for the finished products as packaged, the upper tolerance limits for the moisture and pH for PM0000011 and PM0000012 for the finished packaged products are in Table 5a-2. This information has previously been provided in our December 3, 2014 response to November 12, 2014 Advice/Information Request, additional clarifying question 8, at page 18 in "Table 8-1, Updated Table 3-2 (20141112) Additional Product Characteristics".

Table 5a-2. Finished packaged product upper tolerance limits for moisture and pH.

	General Dry Mint Portion Original Mini (SKU 4800, PM0000011)	General Portion Original Large (SKU 4880, PM0000012)
Upper tolerance limit for moisture	(b) (4)	
Upper tolerance limit for pH		

Swedish Match response to Additional Clarifying Question 5.b. for PM0000010-PM0000017:

It is our practice to release products that (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) . ((b) (4) (b) (4) is provided in **Attachment Q5b1-20150605** for PM0000010, PM0000013-PM0000014, and PM0000015-PM0000017.

For PM0000013 and PM0000015 please see measured a_w values for MR0000024 and MR0000027, respectively, in Attachment Q5b1-20150605.

No a_w data for snus blends before the blend is released for packaging is available for PM0000011-PM0000012. (b) (4) (b) (4) . PM0000011 is packaged as a dry product so only finished product a_w is collected. PM0000012 receives (b) (4) so only the finished product a_w is collected.

To view data demonstrating finished products meet the specifications, we refer CTP to "Figure 17-1. Data demonstrating finished product meets the specifications", pages 35-39 in our December 3, 2014 response to November 12, 2014 Advice/Information Request, additional clarifying question 17.

Swedish Match response to Additional Clarifying Question 5.c. for PM0000010-PM0000017:

The specification for the (b) (4) for production batches having (b) (4) (b) (4) is the same for production batches that are within specification. It is also the same for finished package products (b) (4)

Swedish Match response to Additional Clarifying Question 5.d. for PM0000010-PM0000017:

The instructions in the QEMS indicate that (b) (4) . This is accurate. It is our practice to release products that are (b) (4) . Therefore, as described in the MRTPA, if (b) (4) .

The QEMS does not indicate that (b) (4) . As indicated in the MRTPA, (b) (4) . The QEMS shall be updated to further clarify actions to be taken when (b) (4) . (b) (4) .

Stability profile information (b) (4) is provided below to support that the (b) (4) specifications ensure the same stability profile (b) (4)

PM0000016 and PM0000017

Results from Swedish Match Chemical Control (CAS) program supports that (b) (4) . As seen in Table 5d-1, the (b) (4) .

Table 5d-1. (b) (4)

Article	Storage condition	Age w								TSNA (Sum NNN NNK)¤ (ppm as is)	Moisture content (%)	pH
PM0000016	(b) (4)											
PM0000016												
PM0000017												
PM0000017												

PM0000014

Shelf life study where the (b) (4) demonstrates same stability profile. Table 5d-2.

Table 5d-2.

Article	Storage condition	Age w	(b) (4)	TSNA (Sum NNN NNK)¤ (ppm as is)	Moisture content (%)	pH
PM0000014	(b) (4)					
PM0000014						
PM0000014						
PM0000014						
PM0000014						
PM0000014						
PM0000014						
PM0000014						

PM0000010-PM0000013 and PM0000015

Swedish Match has not experienced a situation where a_w was above the upper limit and bacteria content was within specification for PM0000010-PM0000013. As explained above in response to 5.b., this condition is not applicable to PM0000011-PM0000012 as snus blend a_w is not measured. Swedish Match has not experienced the described condition for PM0000010 and PM0000013 so as to be able to collect stability data. Swedish Match has experienced the described condition for PM0000015 and has no data to demonstrate stability in the described condition. Nonetheless, our practices as described above would not allow (b) (4)
(b) (4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

June 12, 2015

ADVICE/INFORMATION REQUEST

Swedish Match North America, Inc.
Attention: Gerard Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219

FDA Submission Tracking Number (STN): MULTIPLE STNs, see below

Dear Mr. Roerty:

Please refer to your Premarket Tobacco Applications (PMTAs) received March 11, 2015, submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the following tobacco products:

STN	TOBACCO PRODUCT NAME
PM0000010	General Loose
PM0000011	General Dry Mint Portion Original Mini
PM0000012	General Portion Original Large
PM0000013	General Classic Blend Portion White Large - 12ct
PM0000014	General Mint Portion White Large
PM0000015	General Nordic Mint Portion White Large - 12ct
PM0000016	General Portion White Large
PM0000017	General Wintergreen Portion White Large

We also refer to your following amendments:

- June 3, 2015, containing your responses to the May 20, 2015 Advice/Information request letter
- March 30, 2015, containing original specimen labels for the tobacco product referenced in each application

Based on our review of your PMTAs, we have identified the following issues for which we believe additional information or clarification will be helpful to FDA in performing a complete substantive review. We are reviewing your application and the supporting information consistent with the requirements of section 910 of the FD&C Act. These comments are provided as a notice of issues identified to date and do not reflect a final decision on your application.

We note that the following issues have been previously requested in an Advice/Information request letter dated June 5, 2015 related to MR0000020-MR0000029. We have not yet received an amendment to your Modified Risk Tobacco Product Applications (MRTPAs) through the Document Control Center and without your amendment to the MRTPAs addressing all information requests, your PMTAs are also missing similar items. Therefore listed below are issues that are identified to date for your PMTAs. If these issues are satisfied through an amendment to your MRTPAs, in your response please indicate the date of submission and location of your submitted information that satisfies the following issues:

1. All of your portioned PMTAs provide information on the design parameters for the new products. However, you do not include pouch paper porosity and wicking, which are needed to fully characterize the products. Pouch paper porosity and wicking are inherent to the material of the pouch and are major factors in nicotine release. Once the pouch is placed in the user's mouth, the porosity and wicking of the pouch control the amount and rate of nicotine absorption. Therefore, the pouch paper must have defined porosity and wicking specifications or another comparable specification. Demonstrate that target specifications are implemented and adhered to during manufacturing. For PM0000011-PM0000017, provide the target specification and upper and lower range limits for pouch paper porosity (CU) and pouch paper wicking or another comparable specification.

   Additionally, confirm the target specifications are met by providing the test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance (pass/fail) criteria, data sets, and a summary of the results for pouch paper porosity (CU) and pouch paper wicking or another comparable specification for PM0000011-PM0000017. Certificates of analysis from the material supplier may satisfy this deficiency. If you choose to address this part by providing certificates of analysis for the parameters listed above, the certificates of analysis must include a target specification; quantitative acceptance criteria; parameter units; test data average value; and either the standard deviation of the test data or the minimum and maximum values of the test data.

2. All of your PMTAs provide the performance criteria and design parameter test data. However, you do not include all of the information needed to fully characterize the new products. In order to adequately characterize the new products, it is necessary to evaluate the testing procedures. You stated that you submitted the protocol for pouch weight (portion mass) measurements for PM0000013-PM0000017; however, no protocol was found in the June 3, 2015 amendment. Additionally, you do not provide test protocols for portion length, width, and thickness for PM0000011-PM0000017. Provide the protocol documents for measuring the following design parameters:

   a. Pouch weight (portion mass) for PM0000013-PM0000017
   b. Portion length, width, and thickness for PM0000011-PM0000017

3. All of your PMTAs include information confirming that the quality control tests are executed and some of the performance criteria are met. However, clarification is required for some of the performance criteria. Provide the following information:

a. In PM0000010-PM0000012 and PM0000014, the can weights are outside the performance criteria range limits. Since performance criteria are the pre-specified limits to establish product-to-product consistency, the resulting test data must conform to the limits to ensure quality control among the products is regulated. It is unclear why the can weights are out of specification. Therefore, provide a justification for these discrepancies.

b. In PM0000013-PM0000017, you do not provide test data fo(b) (4) stating that a specification does not exist for this parameter. However, in the original submission, you provided a performance tolerance value fo(b) (4) (b) (4) of(b) (4) in Table 3-39. If there is a tolerance value for this quality control parameter, then corresponding test data should exist. Provide(b) (4) quality control test data (i.e., measured values of quality control tests), including data sets and a summary of the results for PM0000013-PM0000017. Certificates of analysis from the material supplier may satisfy this deficiency. If you choose to address this deficiency by providing certificates of analysis for any of the parameters listed above, the certificates of analysis must include performance criteria values; parameter units; test data average value; and either the standard deviation of the test data or the minimum and maximum values of the test data. If you do not have specifications fo(b) (4) , explain why you included performance tolerance value fo(b) (4) of(b) (4) in the original submission.

4. All of your PMTAs include design parameter test data, confirming that the target specifications are met. However, the test data for the portion dimensions are inconsistent. Some of the test data for portion length, width, and thickness falls within the range limits for the new products, but some of the data does not fall within the range limits. You recognize that some of the test data is outside of the specification range limits, stating that the portion dimensions are not release criteria and in turn, the test data is acceptable. However, range limits are used to characterize the product based on the target specifications and product attributes (e.g., taste, use, and HPHC limits). Test data demonstrate if the product conforms to the standards. When manufacturing data does not fall within the range limits of the specification, it is an indication that deviations are occurring (e.g., raw materials are out of specification, equipment malfunction). Regardless of whether the parameter is a release criterion, the test data should be representative of the range limits. Provide a justification for these discrepancies.

5. All of your PMTAs report that your company employs an automatic control system for approval of snus blends before the blend is released for packaging. This automatic control system assesses the values of moisture content, pH, a_w, and sensory characteristics. The analytical values are compared with the specifications, and snus blends having analytical values within the specified tolerance limits are immediately approved.(b) (4) (b) (4) (b) (4) However, the specifications provided in your PMTAs do not include upper tolerance limits for moisture

or pH for the new products in PM0000011 and PM0000012. Furthermore, during FDA inspection of your manufacturing and testing facilities on April 13-17, 2015, it was discovered that QEMS instruction titled (b) (4) (b) (4) " for handling the out-of-specification situations seems to be inconsistent with the procedure described in your PMTAs. The instructions in this QEMS indicate that in (b) (4) (b) (4) Therefore, the following information is needed:

a. Upper tolerance limits for moisture and pH for the new products in PM0000011 and PM0000012.
b. Measured values for a_w for all new products.
c. Specifications for the (b) (4) (b) (4)
d. Information and data to support that th (b) (4) specifications ensure the same stability profile as th (b) (4) (b) (4)

In order to facilitate timely review of your applications, we request that you submit the information identified above within 14 days of the date of this letter. If you anticipate you will need additional time, please contact us to discuss.

Your submission should include a cover letter that includes the following text in your subject line: **RESPONSE TO ADVICE/INFORMATION REQUEST for PM0000010-PM0000017.** When responding, we request that your submission be organized in the following manner to easily identify your responses to each item above:

- List each number and full deficiency text as stated above, and provide your response immediately following the deficiency
  - Your response should address all STNs identified in a deficiency; if different information/data is being submitted for different STNs in your response to a given deficiency, the response should clearly correlate information/data to the applicable STN(s)
  - If submitting a large amount of data to address a deficiency, submit the data as an appendix/appendices and reference the appropriate appendix/appendices in your response
  - If submitting publication(s) to address a deficiency, submit the publication(s) as an appendix/appendices and reference the appropriate appendix/appendices in your response
  - If resubmitting information previously submitted (e.g., tables) to correct earlier omissions/errors, clearly identify what information has been revised
  - If you have already submitted any of the information requested in the deficiency, identify *the date of the prior submission*, page number(s), and line numbers where the requested information is located
- All pages in your submission should be consecutively numbered

We remind you that all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (www.fda.gov/esg) using eSubmitter or mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

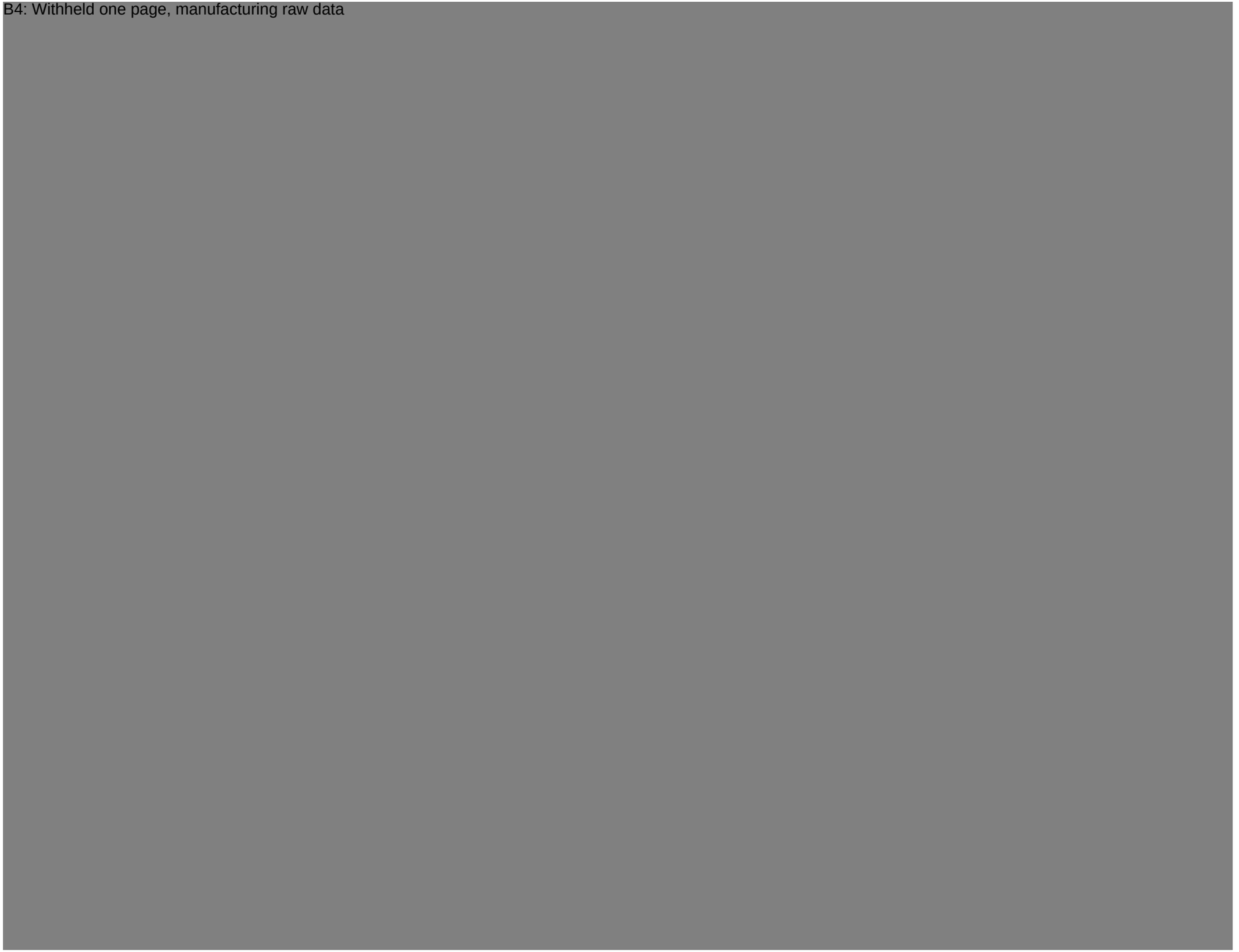
We are unable to accept regulatory submissions by electronic mail.

If you have questions regarding these PMTAs, you may contact Asia Brown, Regulatory Health Project Manager, at (240) 402 – 3833.

Sincerely,

Digitally signed by Ilun Chen -S
Date: 2015.06.12 10:58:05 -04'00'

Ii-Lun Chen, M.D.
Director, Division of Individual Health Science
Office of Science
Center for Tobacco Products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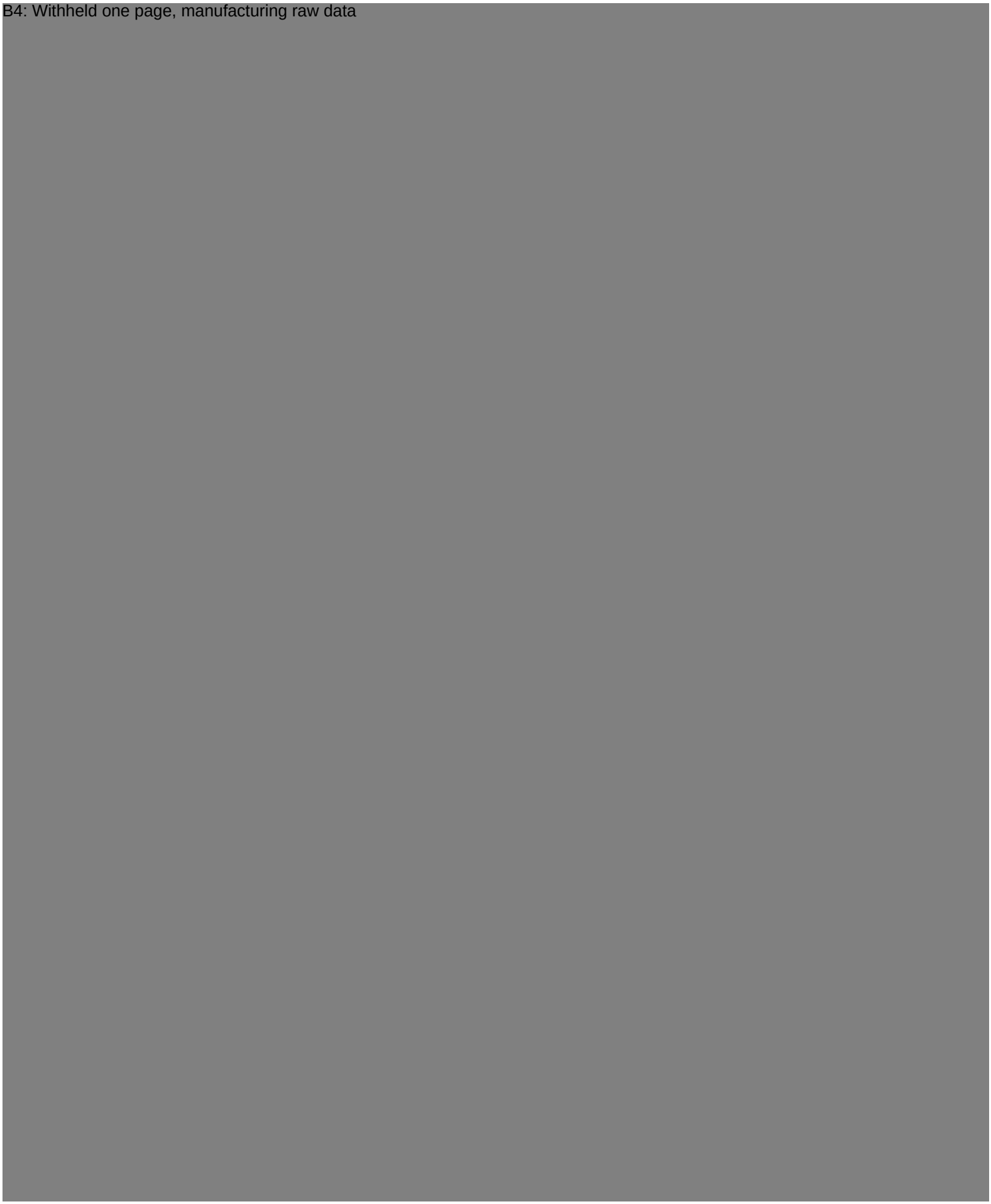

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