

1 October 30, 2020

2
3 Gerard J. Roerty, Jr.
4 Vice President, General Counsel & Secretary
5 SWEDISH MATCH USA, INC.
6 Two James Center
7 1021 East Cary Street, Suite 1600
8 Richmond, VA 23219
9 Phone: 804-787-5100
10 e-mail: Gerry.Roerty@Swedishmatch.com
11

12 FOOD AND DRUG ADMINISTRATION
13 CENTER FOR TOBACCO PRODUCTS
14 Document Control Center
15 Building 71, Room G335
16 10903 New Hampshire Avenue
17 Silver Spring, MD 20993-0002
18

19 **SUBJECT: PERIODIC REPORT for STN PM0000010**

20
21 Dear Sir or Madam:

22 Swedish Match USA, Inc. ("Swedish Match" or "we") writes in regard to FDA's Marketing Order
23 PM0000010 for General Loose ("PM0000010"), included below as **Attachment A.2020-PM0000010**.

24 Section 910(f) of the FD&C Act requires a Postmarket Annual Report be submitted to FDA for any
25 tobacco product in US commerce by virtue of a Marketing Order issued under section 910(b) of the FD&C
26 Act. Swedish Match previously notified FDA of the discontinuance of PM0000010 in correspondence dated
27 March 1, 2018 (**see Attachment B.2020-PM0000010**). The product has not been reintroduced in the U.S.
28 market and thus, no Postmarket Annual Report is required for the 12-month period from October 1, 2019
29 through September 30, 2020 for PM0000010.

30 Furthermore, Swedish Match acknowledges its obligation to contact the Office of Science to discuss
31 if additional information is necessary should we decide to reintroduce PM0000010 into US commerce at
32 some future date.
33

34 For recordkeeping purposes, Swedish Match provides the following information relative to
35 PM0000010 for the 12-month period from October 1, 2019 through September 30, 2020:

STN	PM0000010
Tobacco Product Name	General Loose
Applicant	Swedish Match
Date of Report	10/30/2020
Reporting Period	10/1/2019 – 9/30/2020
Marketing Order Status USA	Not marketed in U.S. Last U.S. distribution date 6/12/2017.
Marketing Status Outside USA	Commercially distributed in Sweden. No sales in E.U. member states. All other sales as governing law permits.

36
37 Swedish Match submits that this submission and the information we are supplying in connection
38 with this Report, are trade secret, proprietary information that is protected under state and federal law
39 from public disclosure. This information should therefore be handled in accordance with the security
40 procedures adopted by FDA in connection with enforcement of the FD&C Act.

41 If further information is required, please contact us.

42 Sincerely yours,

43 (b)(6)
44

45 Gerard J. Koerty, Jr.

46 Vice President, General Counsel & Secretary

47 Document Attachments:

48 Attachment A.2020-PM0000010 – Marketing Order PM0000010

49 Attachment B.2020-PM0000010 – Notification of Discontinuance of PM0000010



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MARKETING ORDER

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
via Certified Mail

FDA Submission Tracking Number (STN): PM0000010

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed the review of your Premarket Tobacco Product Application (PMTA) submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

Table with 2 columns: Attribute and Value. Attributes include Applicant, Tobacco Product Name, Tobacco Product Category, Tobacco Product Sub-Category, Package Type, Package Quantity, Characterizing Flavor, and Tobacco Cut Size. Values include Swedish Match North America, Inc., General Loose, Smokeless Tobacco, Loose Snus, Cardboard Can with Plastic Lid, 45.0 g, None, and (b)(4).

Based on our review of your PMTA, we find permitting the new tobacco product specified above to be marketed is appropriate for the protection of public health, and that you have met the other requirements of section 910(c) of the FD&C Act. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above with the enclosed labeling.

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

2 The applicant provided fraction scale weight buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single value and corresponding range limit.

RECORD RETENTION

Under section 910(f) of the FD&C Act, we are requiring in this order that you retain the records listed below for a period of not less than 4 years from the date of distribution of the last batch of the new tobacco product specified above. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request:

- PMTA submitted prior to product order
- Postmarket reports/postmarket status reports submitted to FDA, including adverse experiences and all relevant documentation associated with the experience
- Correspondence with FDA pertaining to authorized product
- Nonclinical or clinical study documentation including:
 - study protocols (including statistical analysis plan);
 - amendments showing the dates and reasons for each protocol revision;
 - Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals;
 - Informed consent forms;
 - Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC;
 - Investigator financial disclosure statements;
 - Progress reports;
 - Monitoring reports;
 - Adverse experience reports;
 - Case report forms/subject diaries/medical records/laboratory reports;
 - Subject data line listings/observations records;
 - Test article accountability records;
 - Study results/protocol summaries/study reports; and
 - Certifications and amendments to certifications.
- Records pertaining to the manufacture, in process and release testing, process (including any changes to the process, facility, or controls), packaging, and storage of product
- Records pertaining to the sale, marketing, distribution, or other disposition of the product
- Specimens of all labeling, labels, inserts/onserts, instructions, and other accompanying information
- Hazard analysis

POSTMARKET REPORTS

I. Serious and Unexpected Adverse Experiences Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and the tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through a response to a customer complaint, request, or suggestion made as a result of an adverse experience, tobacco product defect, or failure reported to you; or identified in the literature or media. Your information should be submitted with a cover letter that includes the following text in the subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for STN PM0000010.**

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For purposes of reporting under this order, serious adverse experience means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of reporting under this order, unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

II. Manufacturing Deviations

You should promptly investigate all manufacturing deviations, including but not limited to those associated with processing, testing, packing, labeling, storage, holding and distribution. For products that have been distributed, if the deviation may negatively impact public health, you must promptly identify and report that deviation to the Center for Tobacco Products. See instructions below for submitting your regulatory correspondence.

III. Periodic Reporting

Under section 910(f) of the FD&C Act, we are requiring in this order that you submit, on an annual basis, beginning October 2016, unless otherwise notified, the following information in a postmarketing annual report to help FDA determine whether continued marketing of your tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending such order. For the 12- month reporting period, the report must include:

1. A single submission with a cover letter that includes the following text in your subject line: **PERIODIC REPORT for STN PM0000010**. The cover letter should include the STN and corresponding tobacco product name, applicant name, date of report, reporting period, and marketing order status outside the United States.
2. A summary of how the tobacco product continues to be appropriate for the protection of the public health which includes:
 - a. A status report of ongoing studies and a summary of completed studies about the tobacco product conducted by, or on behalf of, the applicant;

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- b. A summary of significant findings on publications not previously reported and include full articles. Any new scientific data (published or otherwise) should also be reported on the likelihood of product use by current users of tobacco products within the same tobacco product category, current users of tobacco products in other tobacco product categories, former users of any tobacco product, and youth and young adults;
 - c. A summary of adverse experiences with this tobacco product reported to you, providing a listing and analysis (accompanied by a statement of any changes to the reference risk information and a summary of important risks, including the nature, frequency, and potential risk factors) of all adverse experiences including those serious and unexpected adverse experiences reported previously.
 - d. A summary of sales and distribution of the tobacco product: Total U.S. sales reported in dollars, units, and volume with breakdowns by US census region, major retail markets, and channels in which the product is sold (e.g., convenience stores, food and drug markets, big box retailers, internet/online sales, tobacco specialty shops);
 - e. Data on current product users. Data should be collected about new users, current users, those who have switched tobacco products, and multiple product users. The results should be broken down by key demographic variables including age, gender, and race/ethnicity. Also, any change in the intended target market for the product should be reported. The data described above may include sales data and post-marketing analysis.
 3. A description of each change made to the manufacturing, facilities or controls during the reporting period, including:
 - a. A comparison of each change to what was described in the PMTA;
 - b. The rationale for making each change; and
 - c. A certification that the reported change did not result in any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of the tobacco product; the basis for concluding that each change did not result in any modification to the final product.
 4. A summary of all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution and indicate a deviation that may affect the characteristics of the final product.
 5. Full-color copies of all advertising for the tobacco product that has not been previously submitted, along with the original date the advertisements were first disseminated and the date the advertisements were discontinued; and
 6. In all annual reports, include a description of any or all labeling changes and submit revised full color final printed labeling.
 - a. The labeling should include all the panels, be presented in the actual size and color with legible text.
 - b. For the first annual report only, submit all final printed labeling (actual labeling for each required warning distributed with the product); include labels, inserts/onserts, instructions, and other accompanying information or materials for this product.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

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This order authorizing the marketing of this new tobacco product does not mean FDA “approved” the new tobacco product specified above; therefore, you may not make any express or implied statement or representation directed to consumers that conveys, or misleads or would mislead consumers into believing, among other things, that the new tobacco product specified above is “approved” by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to withdrawal or temporary suspension under section 910(d) of the FD&C Act.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also packaging, labeling, and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with these applicable statutes and regulations.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution this tobacco product and later decide to reintroduce the product into the market, please contact the Office of Science to discuss if additional information is necessary.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at <http://www.fda.gov/TobaccoProducts>. You may also obtain information by contacting FDA’s Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (<http://www.fda.gov/esg>) using eSubmitter or by mail 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.

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If you have questions, you may contact Asia Brown, MHSA, Regulatory Health Project Manager, at (240) 402-3833.

Sincerely,

Digitally signed by David Ashley -S

Date: 2015.11.10 05:58:03 -05'00'

David L. Ashley, Ph.D.

RADM, US Public Health Service

Director

Office of Science

Center for Tobacco Products

Enclosure

General Loose Labeling



March 1, 2018

Gerard J. Roerty, Jr.
Vice President, General Counsel & Secretary
SWEDISH MATCH USA, INC.
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
Phone: 804-787-5100
e-mail: Gerry.Roerty@Swedishmatch.com

FOOD AND DRUG ADMINISTRATION
CENTER FOR TOBACCO PRODUCTS
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

SUBJECT: RESPONSE TO INFORMATION REQUEST for PM0000010

Dear Sir or Madam:

Swedish Match USA, Inc. (“Swedish Match” or “we”) writes in response to the Food and Drug Administration Center for Tobacco Products (“FDA” or “Agency”) email request of February 28, 2018, included below as **Attachment A-20180301**, (the “Request Letter”) regarding the 2017 Postmarket Annual Report for PM0000010 (“the Report”), General Loose, dated October 27, 2017.

Swedish Match submits this response in order to confirm General Loose, PM0000010, is no longer marketed in the US. To clarify, General Loose, PM0000010, was manufactured in Sweden and imported for distribution in the US. The final production of PM0000010 in Sweden for the US market was the week of May 15-17, 2017. The final shipment of PM0000010 from Sweden to the US was May 18, 2017. Swedish Match received the last US customer order for PM0000010 on June 9, 2017 and that order was shipped (i.e. distributed in the US) June 12, 2017. PM0000010 has a 14 week shelf life. Based on its production date (i.e. May 15-17, 2017), it would have expired at retail by August 24, 2017. At that point, retailers may have returned or destroyed any remaining inventory.

As part of this response, Swedish Match would also like to clarify that the sale of General Loose has not been discontinued outside the US as indicated in the Report, table page 1, lines 28-29. We regret that information from Sweden regarding the expected last production date (e.g. week 20 2017) was inadvertently misinterpreted and incorrectly included on this table as 1/20/2017. A corrected table intended to replace and supersede the table on page 1, lines 28-29, of the Report dated October 27, 2017 is included in this Response (**see Attachment B-20180301**).

If further information is required, please contact me.

Sincerely yours,

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Gerard J. Roerty, Jr.

Vice President, General Counsel & Secretary

Attachments:

Attachment A-20180301 – 2/28/2017 Email Request from S. Ahmad of FDA, CTP, Office of Science

Attachment B-20180301 – Corrected table, page 1, lines 28-29, of the Report dated October 27, 2017

From: Ahmad, Shireen [<mailto:Shireen.Fotelargias@fda.hhs.gov>]
Sent: Wednesday, February 28, 2018 4:11 PM
To: Roerty Gerry <gerry.roerty@swedishmatch.com>
Subject: PM0000010

Hi Gerry,

I had a quick question about PM0000010, General Loose. Is it still marketed in the US? Ranjeeta Gupta says she recalls speaking with you about it being discontinued, but there is no documentation.

Thank you,

*Shireen Ahmad, MS
Regulatory Health Project Manager, Branch IV
Division of Regulatory Project Management
Office of Science, Center for Tobacco Products
U.S. Food and Drug Administration
(240)402-0435*

Periodic Report for the following tobacco product:

STN	PM0000010
Tobacco Product Name	General Loose
Applicant	Swedish Match
Date of Report	10/3/2017
Reporting Period	10/1/2016 – 9/30/2017
Marketing Order Status USA	In market date is 1/20/2014
Marketing Status Outside USA	Commercially distributed in Sweden. No sales in EU member states. All other sales as governing law permits.