

9 PROPOSED POST-MARKET SURVEILLANCE PROGRAM FOR CAMEL SNUS PRODUCTS UNDER A MODIFIED RISK TOBACCO PRODUCT ORDER

9.1 Background

RJRT is seeking a Modified Risk Tobacco Product (MRTP) order from FDA for six Camel Snus product styles.¹ Under this order, RJRT proposes to conduct post-market surveillance to monitor Camel Snus production and to assess the impact of the MRTP order on consumer perceptions, behavior and health.² The goal of post-market surveillance and studies is to identify and collect information regarding any unanticipated and undesired events related to the tobacco product once it is introduced to the market ([FDA MRTPA Draft Guidance 2012](#), p. 29). Post-market surveillance and studies also enable FDA to review the accuracy of the determinations upon which an MRTP order was based. Therefore, post-market surveillance is an important tool for monitoring the effects of the MRTP on individual and population health ([FDA MRTPA Draft Guidance 2012](#), p. 30).

RJRT's approach to its proposed post-market surveillance program is informed by the principles and practices of leading national and international public health agencies. For example, the proposed program plan will follow a flow of activities similar to that provided by the Centers for Disease Control³ and the World Health Organization⁴ which is presented in [Figure 9-1](#).

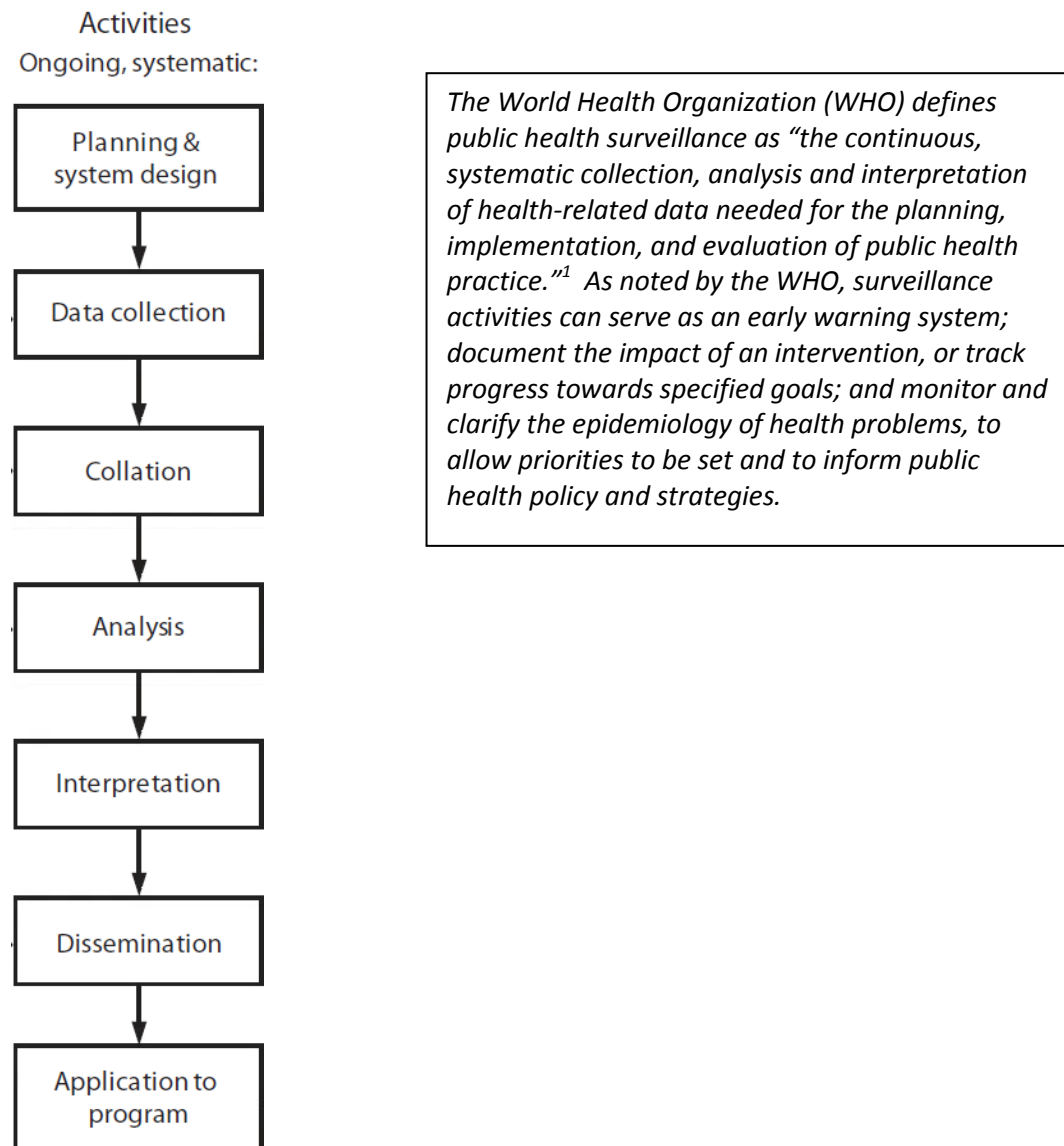
¹ Camel Snus Frost, Camel Snus Mint, Camel Snus Mellow, Camel Snus Frost Large, Camel Snus Winterchill, and Camel Snus Robust. Each Camel Snus brand style has three proposed advertising executions.

² "These postmarket surveillance and studies allow for evaluation of the effect of issuance of an order on consumer perception, behavior, and health, and enable FDA to review the accuracy of the determinations upon which the order was based." [FDA MRTPA Draft Guidance 2012](#), p. 29.

³ [CDC MMWR, CDC's Vision for Public Health Surveillance in the 21st Century, 2012.](#)

⁴ [World Health Organization, Public health surveillance, 2012.](#)

Figure 9-1: Public Health Surveillance System Activities



9.2 Goals of Post-market Surveillance for Camel Snus

The goals of the post-market surveillance for Camel Snus are to:

1. Identify and collect any unanticipated and undesired events (including manufacturing deviations) related to the tobacco product once it is introduced to the market; and
2. Monitor perceptions and use of the products in-market and evaluate their benefit(s) and risk(s) on the health of individuals and on the population as a whole.

9.3 Monitoring

The following elements are proposed for the monitoring activities for post-market surveillance for Camel Snus (see [Table 9-1](#)).

Table 9-1: Elements of the Monitoring Activities for Camel Snus under an MRTP Order

Assessment Elements	Monitoring Activities
(1) Manufacturing deviations	Document incident manufacturing deviations from application specifications Report to CTP on an annual basis
(2) Adverse event reports	Collect consumer complaints and adverse event reports from consumers and FDA reporting Report non-serious adverse events and consumer complaints to CTP on an annual basis Report any serious adverse event (SAE) to CTP within 15 business days of receipt by RJRT
(3) Scientific publications which include Camel Snus information on perceptions, behavior and health	Collect and review publications that address use of the Camel Snus products included under the MRTP Order Report to CTP annually
(4) Report of ongoing RJRT sponsored scientific studies (and a summary of completed studies) about the product	Develop a report of all ongoing scientific studies, and a summary of all completed studies, involving the Camel Snus products included under the MRTP Order Report to CTP annually
(5) Sales and distribution data	Collect annual sales and distribution data for the Camel Snus products included under the MRTP Order Report to CTP annually
(6) Data on current Camel Snus users	Conduct surveys of current users of the Camel Snus products included under the MRTP Order Report to CTP annually
(7) Data on current, former, and never tobacco users	Report to CTP annually
(8) Update Dynamic Population Modeler, DPM(+1)	Report to CTP annually

9.4 Detailed Description of Assessment Elements (Data Collection)

This section presents a detailed description of the assessment elements described in [Table 9-1](#) above. RJRT proposes submitting annual reports to FDA that include information on each of the assessment elements. RJRT will submit the annual reports to FDA in the format and in the timetable agreed upon with the Agency. Each report will summarize the information from each assessment element and provide an ongoing assessment of how the Camel Snus products included in an MRTP order impacts the health of individuals and the population as a whole, taking into account both users and non-users of tobacco products.

9.4.1 Manufacturing deviations

(b) (4)



9.4.2 Adverse event reports

RJRT, through a contract vendor, collects information from the public regarding its products. A listing and analysis of all consumer complaints reported to RJRT that involve a Camel Snus product included in the MRTP Order will be reported to FDA annually (b) (4)

(b) (4)



RJRT's experience from sponsored clinical studies and a review of the literature suggest that adverse events related to snus use are generally mild. RJRT will report all Camel Snus adverse events from any active clinical studies of Camel Snus on an annual basis.

FDA has developed a reporting system for tobacco products which encourages reports about tobacco products that are contaminated, damaged, defective, or associated with unexpected health or safety effects. RJRT will submit an annual FOIA request to FDA CTP for any Camel Snus specific information for review and inclusion in RJRT's Post-Market Surveillance annual report.

(b) (4)



(b) (4)

⁵ RJRT will submit these reports through the FDA's Safety Reporting Portal⁶ and through any additional reporting system that FDA establishes for reporting of tobacco associated SAEs. These events will also be summarized in the RJRT's Post-Market Surveillance annual report for Camel Snus.

9.4.3 Scientific publications

RJRT will monitor the scientific literature through quarterly bibliographic searches, for specific publications involving the Camel Snus products included in the MRTP Order. RJRT will also monitor published abstracts of presentations given at leading scientific conferences on tobacco/nicotine⁷ for presentations involving the Camel Snus products included in the MRTP order. Copies of all publicly available publications, as well as documentation available from scientific presentations (*e.g.*, abstracts) will be provided to FDA annually. These publications will be summarized in RJRT's Post-Market Surveillance annual report.

9.4.4

(b) (4)

(b) (4)

9.4.5 Sales and distribution data

Data on sales and distribution of the Camel Snus products included in the MRTP order will be included in the Post-Market Surveillance report. (b) (4)

9.4.6 Data on current product users

Data on current users of the Camel Snus products included in the MRTP order will be provided to FDA on an annual basis. The Post-Market Surveillance annual report will include information on those who are new users, current users, those who have switched to a Camel Snus product

⁵ [Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance 1996.](#)

⁶ [FDA Safety Reporting Portal for Tobacco Products 2016.](#)

⁷ Some examples include Society for Research on Nicotine and Tobacco, American Public Health Association, Society for Behavioral Medicine, and the Tobacco Science Research Conference.

from another tobacco product, and multiple tobacco product users. Data will be provided on demographic variables, including age, gender, and race/ethnicity. Data will be collected through new and ongoing surveys conducted by, or on behalf of, RJRT for the purpose of monitoring and surveillance under the MRTP order. Information on users of the Camel Snus products included in the MRTP order will be collected through several surveillance efforts. These efforts include ongoing surveys of current, former, and never tobacco users (including users of the Camel Snus products). These surveys are described below.

9.4.6.1 National Tobacco Behavior Monitor (Primary)

The National Tobacco Behavior Monitor (NTBM) assesses adult tobacco use behaviors across a number of tobacco products (*e.g.*, cigarettes, smokeless tobacco, e-cigarettes) with an emphasis on initiation, dependence, and cessation. (b) (4)

[REDACTED]

The following data from the NTBM survey will be provided to FDA annually:

- Demographics of Camel Snus users
 - Age; gender; race/ethnicity; education
- Data on product use
 - Use of Camel Snus only
 - Use of Camel Snus with other tobacco product(s)
- Trajectory of product use
 - Initiation of tobacco use with Camel Snus
 - Switch completely from combustible tobacco product(s)
 - Re-initiation (among former tobacco users) with Camel Snus
 - Quitting behavior

9.4.6.2 Total Tobacco Migration Tracker (Secondary)

The Total Tobacco Migration Tracker (TTM) assesses adult tobacco users' attitudes and behaviors across a number of tobacco products (*e.g.*, cigarettes, smokeless tobacco, e-cigarettes) (b) (4)

(b) (4)

(b) (4)

(ages 18 and older) (b) (4)

, (b) (4)

(b) (4)

. The following data from this survey will be provided to FDA annually.

- Demographics (age, gender, race/ethnicity) of Camel Snus users
- Specific Camel Snus product(s) used
- Duration of use (since initiation)
- Amount of use (days used per month, number of pouches per day)
- Quit attempts
- Use of other tobacco products

The methodological report for TTM will be finalized and submitted to the FDA with the final Post-Market Surveillance Program Protocol which is required 30 days after notification of the requirement to conduct surveillance.

9.4.7 Risk Perceptions and Likelihood of Use

Once an MRTP order is granted, current, former, and never tobacco users will be surveyed to assess consumer understanding of the Camel SNUS modified risk messaging, as well as perceptions about the absolute and relative health risk of Camel Snus (and changes in these perceptions, if any), over time. RJRT will also monitor likelihoods of use among current, former, and never tobacco users, and compare these likelihoods to actual use data from post-market surveillance research once it becomes available. RJRT will use existing tools to measure consumer comprehension and perceptions, and likelihoods of use among tobacco users and non-users. Complete details regarding consumer testing (*e.g.*, risk perceptions, likelihood of use) will be provided in the Post-Market Surveillance Program Protocol.

9.4.8 Dynamic Population Model

In this Application, RJRT describes how the results of the likelihood of use studies and projected purchase models were used to estimate future behavior and the overall impact on population health (see [Sections 2.9.5](#) and [6.4](#)). RJRT also described in detail the Dynamic Population Modeler, DPM(+1), which estimates the difference in population-level survival between a counterfactual scenario that allows the use of either a higher-risk product or Camel Snus, and a base case that only allows the use of the higher-risk product (see [Sections 2.9.5](#) and [6.4](#)). An intended, beneficial consequence of widespread MRTP availability is complete switching to MRTP use by some current cigarette smokers who otherwise would have continued to smoke (*i.e.*, product switching). Unintended, harmful consequences of widespread MRTP availability

could include initiation of MRTP use by some never tobacco users who otherwise would have remained never tobacco users (*i.e.*, increased tobacco use) and transitioning to cigarette smoking after initiation of tobacco use with an MRTP by some who would have remained never tobacco users (*i.e.*, gateway to smoking). In this Application, RJRT used the DPM(+1) to examine the magnitude, and thus likelihood, of beneficial consequences required to offset potential population-level survival deficits associated with harmful consequences of increased MRTP availability.

While estimated likelihoods of use were useful for model projections, RJRT anticipates including actual use data collected from the surveillance program to update estimated impact of the MRTP on population health over time. In the Post-Market Surveillance program, RJRT will go beyond predictive data and use real world data on actual use of the MTRP. RJRT anticipates that continued tracking of actual use of the MRTP will provide the data needed to update model projections based on real world transitions. Output from these models will estimate overall net effect and include tipping point analyses. RJRT anticipates providing updated Dynamic Population Modeler, DPM(+1) results either in, or as a supplement to, the Post-Market Surveillance annual report. Considering the timing of collecting, analyzing and summarizing data from all sources, it may be more informative to run models with the most recent and complete data available.

9.5 Collation, Analysis, and Interpretation

In the Post-Market Surveillance Program Protocol, RJRT will detail the plans for collecting and collating the data and specify analysis plans for data sets. As described above, annual reports will include summaries and supporting documentation related to manufacturing deviations; consumer complaints and adverse events; scientific publications and presentations; reports of any ongoing RJRT sponsored studies; data on Camel Snus distribution and sales; data on current product users' behavior; and data on current, former and never tobacco users related to Camel Snus. An interpretation of all the data from multiple sources will be included in the Post-Market Surveillance annual reports on Camel Snus to the FDA.

9.6 Reporting

As described above, RJRT will submit Post-Market Surveillance annual reports on the impact of the MRTP order on consumer perceptions, behavior and health.

9.7 Conclusion

RJRT has provided this summary of its Proposed Post-Market Surveillance Program for Camel Snus Products under an MRTP order with the understanding that applicants granted a risk modification order must submit protocols for required post-market surveillance for FDA concurrence. RJRT understands that FDA may require or suggest alternative or additional surveillance activities or studies to those proposed in this program. Based on agency feedback on this plan and subsequent to an MRTP order, RJRT will submit the final protocol that results in collection of the data or other information FDA determines is necessary to protect the public

health, including data and information that the MRTP continues to satisfy the requirements for the issuance of an order under Section 911(g)(1).