

(b) (4)

## EXEMPT DETERMINATION

**DATE:** 25 Jan 2024

**TO:** (b) (6)

**PROJECT:** Swedish Match North America, LLC - (b) (4)

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### DOCUMENTATION REVIEWED:

- Protocol Version(s):**
- Protocol (Version 1.0, Dated January 16, 2024)
- Consent Form(s):**
- INFORMED CONSENT STATEMENT (Version 1.0, Dated 16-JAN-2024)
- Other Material:**
- WELCOME SCREEN (Dated 16-JAN-2024)
  - MAIN QUESTIONNAIRE (Dated 16-JAN-2024)

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Using the Department of Health and Human Services regulations found at 45 CFR 46.104(d) (2), the IRB determined that your research project is exempt from IRB oversight. All study related documents will be removed from our active files and archived.

Note: You will still be able to access this study via the (b) (4) for three years. After three years, the study will be removed from the system in accordance with IRB regulations.

Please be advised that as (b) (4) is not overseeing the conduct of the study, study materials, documents and reports (b) (4) an IRB. Also, if your study includes subject-facing materials such as consent forms, recruitment materials, and other materials used by subjects in the study, the IRB company name and contact information should not be referenced. Study materials, documents and reports may include a general statement that the study was reviewed by an IRB, such as, "This study has been reviewed by an institutional review board (IRB), which is a committee that has reviewed this research study to help ensure that your rights and welfare as a research participant are protected and that the research study is carried out in an ethical manner."

The IRB granted this exemption with an understanding of the following:

1. The research project will only be conducted as submitted and presented to the IRB, without additional change in design or scope.

2. Should the nature of the research project, or any aspect of the study, change such that the nature of the study no longer meets the criteria found in 45 CFR 46.104(d) (2), you will resubmit revised materials for IRB review.
3. It is the responsibility of each investigator to ensure that the project meets the ethical standards of the institution. Specifically, the selection of subject is equitable, there are adequate provisions to maintain the confidentiality of any identifiable data collected, and when there are interactions with research subjects, they will be informed: that the activity involves research; of a description of the procedures; that participation is voluntary; and of the contact information for the researcher.

The IRB will evaluate the new information and make a determination at that time regarding the research project's status.

This project is not subject to requirements for continuing review.

If you wish to appeal the IRB's determinations and/or imposed modifications, please submit supporting documentation to address the IRB's concerns by (b) (4).

**Compliance Statement/REB Attestation (Applicable for research conducted in Canada):**

The IRB attests that this submission has been approved by an IRB whose membership complies with the requirements defined in Health Canada regulations, ICH GCP guidelines, FDA regulations at 21 CFR part 56, and HHS regulations at 45 CFR part 46. The IRB carries out its functions in accordance with FDA regulations at 21 CFR parts 50, 56, 312, and 812; HHS regulations at 45 CFR part 46, subparts A-E; good clinical practices; Health Canada regulations; and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, as appropriate to the research.

(b) (4) is registered with OHRP and FDA under IRB (b) (4).

If you have any questions or concerns, please use the Contact IRB activity on the (b) (4).

Thank you for selecting (b) (4) to review your research project.

Sincerely,

(b) (6)