



Health
Canada

Santé
Canada

Health Products
and Food Branch

Direction générale des produits
de santé et des aliments

TERMS AND CONDITIONS

Company: Novavax Inc.

Product: Nuvaxovid XBB.1.5 (COVID-19 Vaccine (recombinant protein, adjuvanted))

Dossier ID: HC6-024-E278519

Background:

The Food and Drug Regulations allows the Minister to impose or amend terms and conditions, and request additional information, in relation to a COVID-19 drug submission, Drug Identification Number (DIN), or establishment licence, at any time while it is in effect. In light of the severity of the COVID-19 pandemic, this allows the Minister to act quickly to gather important safety information or mitigate risk in a timely manner.

Depending on the requirement, terms and conditions can be ongoing (e.g., require a monthly report), have a defined time (e.g., a report is due to Health Canada on a specific day) or are to be completed once the data is available (e.g., a clinical trial is completed).

The status of the Terms and Conditions will be updated on a regular basis.

Status as of December 05, 2023:

Total Number: 26

Ongoing/pending: 26

Closed: 00

Table: Terms and Conditions

	Terms and Conditions	Issued	Status
1	Novavax Inc. is required to provide the results from the blinded crossover period including safety and efficacy data for 24 months from participants after the second dose from Study 2019nCoV-301, when the data become available.	December 5, 2023	Pending
2	Novavax Inc. is required to provide the results from the blinded crossover period including safety and efficacy data for 12 months from participants after the second dose from Study 2019nCoV-302, when the data become available.	December 5, 2023	Pending
3	Novavax Inc. is required to provide the safety, efficacy, and immunogenicity results from the adolescent participants from Study 2019nCoV-301, when the data become available.	December 5, 2023	Pending
4	Novavax Inc. is required to update the Product Monograph with information on the pregnancy registry, when the registry is in effect and the weblink is live. The	December 5, 2023	Pending

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	text provided in the clarification request dated 2022-01-14 should be followed for this update.		
5	Novavax Inc. is required to provide data regarding protection against current and emerging variants of concern, when available.	December 5, 2023	Ongoing
6	Final reports of Studies 2019nCoV-301 and 2019nCoV-501 should be provided once available.	December 5, 2023	Pending
7	Vaccine effectiveness following the booster vaccination with Nuvaxovid should be provided once the data become available.	December 5, 2023	Ongoing
8	Provide interim analyses at 1 month of the immunogenicity data from Clinical Study 2019nCoV-313 Part 1 pertaining to the primary, secondary, and exploratory immunogenicity objectives and endpoints as soon as it becomes available as a Supplement to a New Drug Submission (SNDS)/Level II – Supplement.	December 5, 2023	Pending
9	Provide interim analyses at 1 month of the immunogenicity data from Clinical Study 2019nCoV-313 Part 2 pertaining to the primary, secondary, and exploratory immunogenicity objectives and endpoints as soon as it becomes available as a Supplement to a New Drug Submission (SNDS)/Level II – Supplement.	December 5, 2023	Pending
10	Provide interim analyses at 1 month of the safety data from Clinical Study 2019nCoV-313 Part 1 pertaining to the primary, secondary, and exploratory safety objectives and endpoints as soon as it becomes available as a Supplement to a New Drug Submission (SNDS)/Level II – Supplement.	December 5, 2023	Pending
11	Provide interim analyses at 1 month of the safety data from Clinical Study 2019nCoV-313 Part 2 pertaining to the primary, secondary, and exploratory safety objectives and endpoints as soon as it becomes available as a Supplement to a New Drug Submission (SNDS)/Level II – Supplement.	December 5, 2023	Pending
12	Provide interim analyses at 6 month of the immunogenicity and safety data from Clinical Study 2019nCoV-313 Part 1 pertaining to the primary, secondary, and exploratory immunogenicity/safety objectives and endpoints as soon as it becomes available as a Supplement to a New Drug Submission (SNDS)/Level II – Supplement.	December 5, 2023	Pending
13	Provide interim analyses at 6 month of the immunogenicity and safety data from Clinical Study 2019nCoV-313 Part 2 pertaining to the primary, secondary, and exploratory immunogenicity/safety objectives and endpoints as soon as it becomes available as a Supplement to a New Drug Submission (SNDS)/Level II – Supplement.	December 5, 2023	Pending
14	Provide the final CSR for Clinical Study 2019nCoV-313 (Part 1 and Part 2) as soon as it becomes available.	December 5, 2023	Pending
15	Provide interim analyses at 1 month of the immunogenicity data from Clinical Study 2019nCoV-314 pertaining to the primary, secondary, and exploratory immunogenicity objectives and endpoints, along with a post-hoc analysis of the neutralizing antibodies at 28 days post-dose of the “per-protocol	December 5, 2023	Pending

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	immunogenicity” population that received Nuvaxovid XBB.1.5 compared to the historical control of adolescents that received NUVAXOVID (prototype vaccine) as a third booster dose following the Nuvaxovid primary series, as soon as it becomes available as a Supplement to a New Drug Submission (SNDS)/Level II – Supplement.		
16	Provide interim analyses at 1 month of the safety data from Clinical Study 2019nCoV-314 pertaining to the primary, secondary, and exploratory safety objectives and endpoints along with a post-hoc analysis of the safety, namely, 7-day reactogenicity (local and systemic adverse event) and 28-day treatment emergent adverse events, in the safety analysis set population that received Nuvaxovid XBB.1.5 compared to the historical control of adolescents that received NUVAXOVID (prototype vaccine) as a third booster dose following the Nuvaxovid primary series, as soon as it becomes available as a Supplement to a New Drug Submission (SNDS)/Level II – Supplement.	December 5, 2023	Pending
17	Provide interim analyses at 6 month of the immunogenicity and safety data from Clinical Study 2019nCoV-314 pertaining to the primary, secondary, and exploratory immunogenicity/safety objectives and endpoints as soon as it becomes available as a Supplement to a New Drug Submission (SNDS)/Level II – Supplement.	December 5, 2023	Pending
18	Provide the final CSR for Clinical Study 2019nCoV-314 as soon as it becomes available.	December 5, 2023	Pending
19	Provide interim analyses at 120 day, 240 days, 360 days of the immunogenicity data from Clinical Study 2019nCoV-301 pertaining to the SARS-COV-2 vaccine immunogenicity (IgG antibody to SARS-CoV-2 S protein, MN, hACE2 inhibition) as soon as it becomes available as a Post Decision Clearance Data.	December 5, 2023	Pending
20	Provide interim analyses at 120 days, 240 days, 460 days of the safety data from Clinical Study 2019nCoV-301 pertaining to the unsolicited AEs, MAAEs, SAEs, AESIs, PIMMCs and deaths as soon as it becomes available.	December 5, 2023	Pending
21	Novavax Inc. is required to submit Periodic Safety Update Reports (PSURs)/Periodic Benefit Risk Evaluation Reports (PBRERs) every 6 months for Nuvaxovid XBB.1.5, unless otherwise determined by Health Canada.	December 5, 2023	Ongoing
22	Novavax Inc. is required to submit an updated core RMP with the Canadian Addendum in a timely manner if a safety issue is identified that requires immediate regulatory action or as requested by Health Canada. The RMP format should follow the guidance (Guidance Document Submission of Risk Management Plans and Follow-Up Commitments) and should include the following: a. A safety specification that details the identified risks, potential risks, and missing information for Nuvaxovid XBB.1.5;	December 5, 2023	

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	<p>b. A pharmacovigilance plan that details specific measures to be taken to identify and report safety issues in COVID-19 patients, including adverse reaction reporting, periodic reporting, and ongoing/planned studies; and</p> <p>c. A risk minimization plan, if applicable, to manage risks that may require additional measures beyond those considered standard.</p>		
23	Novavax Inc. is required to submit interim and final reports for post-authorization studies 2019nCoV-402 and 2019nCoV-404.	December 5, 2023	Pending
24	<p>Novavax Inc. to provide a summary of the changes made to the website for Health Canada’s review with each update.</p> <p>a. Novavax Inc. to attest that the content of the website is consistent with the approved Canadian-specific labelling information for Nuvaxovid XBB.1.5. (COVID-19 Vaccine (recombinant protein, adjuvanted)) in French and English. The website content related to the appropriate storage & handling and preparation & administration of Nuvaxovid XBB.1.5. (COVID-19 Vaccine (recombinant protein, adjuvanted)) should be aligned with information in the Product Monograph.</p> <p>b. For revisions to the website design and layout related to updates to the indication, use or presentation of the vaccine, Novavax Inc. commits to providing final screenshots of relevant components of the electronic platform (linked to any foreign or Canadian specific Nuvaxovid XBB.1.5. (COVID-19 Vaccine (recombinant protein, adjuvanted)) labels dispensed in Canada), containing the approved Canadian-specific labelling information for Nuvaxovid XBB.1.5. (COVID-19 Vaccine (recombinant protein, adjuvanted)) in French and English for Health Canada’s records, following review and approval by Pharmaceutical Advertising Advisory Board (PAAB).</p>	December 5, 2023	Ongoing
25	<p>Novavax Inc. is requested to develop and distribute a company-led customer communication, in English and French, should a decision be made to import non-Canadian labelled supplies for Canadian sites. The customer communication should aim to inform healthcare professionals that Novavax Inc. will delay the implementation of Canadian-specific inner/outer labels following NDS approval for Nuvaxovid XBB.1.5. (COVID-19 Vaccine (recombinant protein, adjuvanted)), and that interim inner/outer labels will be used for the short term. Please note the following:</p> <p>a. Novavax Inc. should consider including images and texts of these labels in the customer communication and clearly outline all deviations from Canadian requirements;</p>	December 5, 2023	Ongoing

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	<p>b. The customer communication should direct healthcare professionals to the electronic platform where they can find information about the approved Canadian-specific labelling in both official languages</p> <p>c. The customer communication should not resemble a Health Canada-endorsed Health Product Risk Communication and should not reflect a red banner at the top of the document. A company led risk communication may take the form of a letter carrying the company letterhead, for example.</p> <p>The company-led customer communication does not require review by Health Canada; however, Novavax Inc. is welcome to seek courtesy feedback from BRDD. Novavax Inc. is expected to exercise due discretion to ensure prompt finalization and dissemination of the customer communication. Please provide a copy of the final, signed customer communication in English and French via eCTD once available.</p>		
26	<p>Novavax Inc. to commit to implementing Canadian specific bilingual labelling for Nuvaxovid XBB.1.5. (COVID-19 Vaccine (recombinant protein, adjuvanted)) Drug Identification Numbers (DINs) currently marketed in Canada, to be submitted in the agreed upon timeline. Health Canada should be kept informed of estimated timelines and proposed strategies concerning the implementation of Canadian-specific bilingual labels. During the period prior to implementation of the Canadian-specific bilingual labeling, Canadian reference labels should be made available to healthcare professionals.</p>	December 5, 2023	Pending