Importation of Moderna COVID-19 Vaccine with either 10 or up to 15 Doses per Vial and English-only Vial and Carton Labels (US-Labelled Supply)

10/09/2021

Audience
Healthcare professionals including infectious disease physicians, pharmacists, family physicians, public health officials, nurses and nurse practitioners, and healthcare professionals at identified points of use.

GC Pharma is distributing COVID-19 Vaccine Moderna doses directly to vaccination locations where administration of the vaccine will occur, as outlined by provincial and territorial governments and public health authorities.

Key messages

- **Further to the May 21, 2021 Conditional Approval of the COVID-19 Vaccine Moderna, ModernaTx, Inc. is providing US-labelled vaccine supplies with English-only vial and carton labels (see Appendix A) in order to expedite the distribution of the vaccine in South Korea.**
- **Moderna COVID-19 Vaccine with US labels has been authorized by MFDS and it is the same in all aspects (i.e., formulation, strength, route of administration) to the currently approved COVID19 vaccine Moderna.**
- **Healthcare professionals are advised that:**
    - **Information regarding the vaccine name, description of pharmaceutical form, volume of vial fill and storage conditions are different on the US labels. Continue to reference the MFDS approved labelling for all product information for use in South Korea.**
    - **The expiration date is not printed on the US vial and carton labels. Healthcare professionals must verify the expiration date prior to vaccination. The expiration date for the corresponding lots can be found on this website. Please follow the instruction to retrieve the expiration date.**

Information for healthcare professionals

Healthcare professionals should be aware that there are no changes to the product. The indication, dosage, route of administration, strength, formulation, and non-medicinal ingredients in the US-labelled product are the same as the current MFDS authorized COVID-19 Vaccine Moderna.

Healthcare professionals are advised that:

- The US-labelled Moderna COVID-19 Vaccine has a different carton and vial label. Continue to reference the MFDS approved product information for use in South Korea.
- The expiry date is not printed on the vial and carton labels (see Appendix A). **To find the expiration date for Moderna COVID-19 Vaccine lots manufactured in US, please click on the following link and follow the instruction**:

  https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup#vialLookUpTool

- There are no changes to the dosage and administration, other than the total number of doses per vial in the 8 mL presentation.
- There are no changes to the storage, stability and disposal of the vaccine. The US-labelled Moderna COVID-19 Vaccine should be stored and discarded in accordance with the SFDA approved information.

Report health or safety concerns

Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any serious or unexpected side effects in patients receiving COVID-19 Vaccine Moderna should be reported to your local Health Unit.

Original signed by

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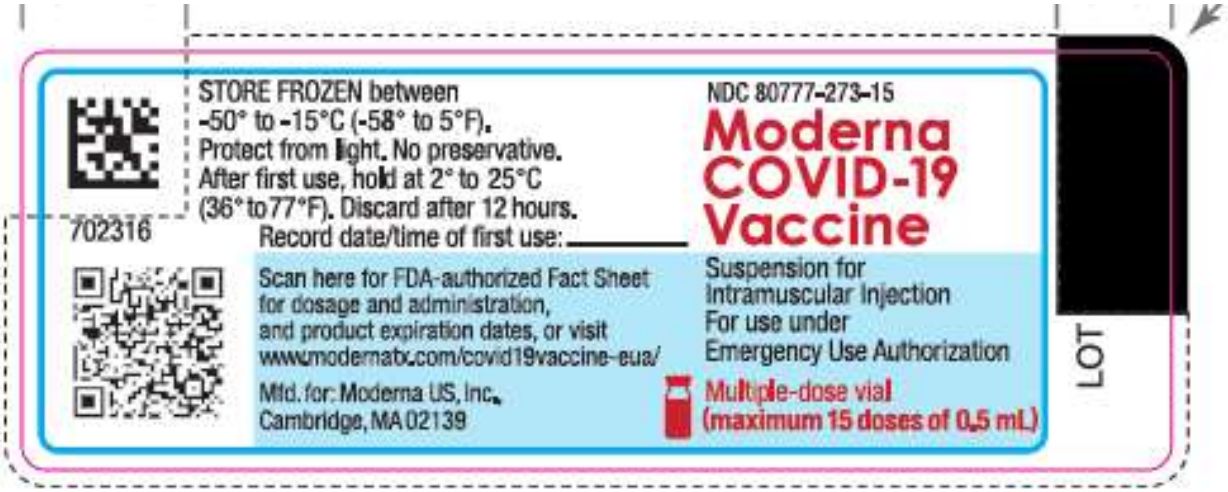
Appendix A – Vial and Carton Labels for Moderna COVID-19 Vaccine with English-only Labelling (US-labelled supply)

U.S. VIAL LABEL



U.S. CARTON LABEL