U.S. FOOD & DRUG ADMINISTRATION

February 21, 2023

Han-bum Park, RA
GenBody Inc.
3-18, Eopseong 2-gil, Seobuk-gu, Cheonan-si,
Chungcheongnam-do, 31077 Republic of Korea

Re: EUA210249/S008
Trade/Device Name: GenBody COVID-19 Ag
Dated: November 15, 2022
Received: November 15, 2022

Dear Han-bum Park:

This is to notify you that your request to update the authorized labeling of the GenBody COVID-19 Ag; (1) in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to revise the authorized use(s) as required and described in Appendix A, and make various updates to the authorized labeling as required and described in Appendix B of the letter, and (2) include with results of additional reactivity studies, is granted. Upon review, we concur that the information submitted in EUA210249/S008 supports the requested updates for use with the GenBody COVID-19 Ag and fulfills Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022. The Fact Sheet for Healthcare Providers and Fact Sheet for Patients have been updated by FDA consistent with this revision and are included along with this letter.

By submitting this supplemental request for review by the Food and Drug Administration (FDA), you have complied with and fulfilled Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022, and complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the GenBody COVID-19 Ag re-issued on August 10, 2022.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Cc: David Yoo, Kwell Laboratories, LLC (U.S. Agent)