U.S. FOOD & DRUG ADMINISTRATION

January 17, 2023

Kyle Rose,
Regulatory Lead
Watmind USA
4780 I 55 N, Suite 450
Jackson, MS 39211

Re: EUA220042/S004
Trade/Device Name: Speedy Swab Rapid COVID-19 Antigen Self-Test
Dated: November 16, 2022
Received: November 16, 2022

Dear Kyle Rose:

This is to notify you that your request to update authorized labeling of the Speedy Swab Rapid COVID-19 Antigen Self-Test; (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 of the letter, and make various updates to the authorized labeling as required and described in Appendix B of the letter, (2) include details of an optional web-based reporting mechanism to address Condition of Authorization S. in the July 8, 2022 Letter of Authorization, and (3) other minor updates for clarification, is granted. Upon review, we concur that the information submitted in EUA220042/S004 supports the requested updates for use with the Speedy Swab Rapid COVID-19 Antigen Self-Test and fulfills Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 and Condition of Authorization S. in the July 8, 2022 letter. The Fact Sheet for Healthcare Professionals has been updated by FDA consistent with this revision and is 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 Speedy Swab Rapid COVID-19 Antigen Self-Test issued on July 8, 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