December 16, 2022

Jonathan Maa
Chief Operating Officer
Maxim Biomedical, Inc.
1500 East Gude Drive, Suite A
Rockville, MD 20850

Re: EUA210663/S009
Trade/Device Name: MaximBio ClearDetect COVID-19 Antigen Home Test
Dated: November 14, 2022
Received: November 15, 2022

Dear Jonathan Maa:

This is to notify you that your request to update the authorized labeling of the MaximBio ClearDetect COVID-19 Antigen Home Test in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to; (1) revise the authorized use(s) as required and described in Appendix A, and (2) make various updates to the authorized labeling as required and described in Appendix B of the letter, is granted. Upon review, we concur that the information submitted in EUA210663/S009 supports the requested updates for use with the MaximBio ClearDetect COVID-19 Antigen Home Test. The Fact Sheet for Healthcare Providers (HCPs) 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.

Sincerely yours,

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