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Microbiologist/Regulatory Scientist
FDA/Center for Devices and Radiological Health (CDRH)
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Division of Microbiology Devices
10903 New Hampshire Avenue
Building 66, Room 4528
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Phone: 301-796-6121
FAX: 301-8478512
Email:michael.white@fda.hhs.gov

Subject: Immediate Response Required-COVID testing without notification or EUA BioTeke

Dear White,

In response to compliance requirements for product launches in the United States or other countries, the Company is developing regulations to govern sales practices, including but not limited to an overall review of the Company's promotional materials (official website, colouring pages, etc.), investigation of distributors' sales destinations, adoption of clauses in contracts to bind the destination country, and carrying out QR code information for product traceability, among other means. The first three of these methods have already been implemented by the Company, and the fourth way is designed to address the supply of third-party service providers, and we are discussing options.

Based on your suggestions, "This product is not available for US market " has been added in our website and product colouring sheets, please refer to it.

Last, any product that does not have EUA, 510k or required clearances is not exported to the USA and if found in the US market is an impostor.

Our company has invested a great deal of attention in compliance with the product launch, please allow us to correct and work on it.

BioTeke Corporation (Wuxi) Co., Ltd
14/12/2021