U.S. FOOD & DRUG ADMINISTRATION

July 27, 2018

UPS EXPRESS MAIL

Mr. Mike Colwill
Head Start Solutions
529a Riddell Road
Glendowie
Auckland 1071
New Zealand

Dear Mr. Colwill:

The Office of Compliance and Biologics Quality in the Center for Biologics Evaluation and Research of the United States Food and Drug Administration (FDA) has reviewed your Internet website http://www.testkitlabs.com. Your website promotes the iCare HIV 1&2 Rapid Screen Test. Copies of the pertinent Internet website pages are enclosed for your reference.

HIV test kits are medical devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) because they are in vitro diagnostic instruments intended for use in the diagnosis of disease. Under section 513(f) of the Act, the devices are class III devices, which under section 501(f)(1)(B) are deemed to be adulterated unless they have received premarket approval under section 515 or an investigational device exemption (IDE) under section 520(g). These statutory provisions protect the public health and help ensure that new medical devices are safe and effective.

The device promoted on your Internet website is not approved for sale in the United States and has not received an investigational device exemption from premarket approval. The Internet website above does not exclude the sale of the HIV test kit in the United States. Instead, your website appears to promote the iCare HIV 1&2 Rapid Screen Test to buyers in the United States. For example, your website sells the device in U.S. dollars. Moreover, the United States is included in the "drop-down" box on the payment page, inviting orders for shipment of the product to the United States.

The introduction, or delivery for introduction, of the iCare HIV 1&2 Rapid Screen Test into interstate commerce in the United States would be violative under sections 301(a) and 501(f)(1)(B) of the Act.

Additionally, product labeling that is false or misleading in any particular renders a device misbranded under section 502(a) of the Act. If you introduce, or deliver for introduction, a misbranded device into interstate commerce in the United States, you would be doing so in violation of section 301(a) of the Act. We are concerned about the accuracy of the iCare HIV 1&2 Rapid Screen Test product labeling, specifically the statements:

">99% Sensitivity and >99% Specificity;" and

"Reliable and Fast Results in <15 minutes."

You should take prompt action to correct the violations referenced above. To avoid violating the Act, you must refrain from introducing the iCare HIV 1&2 Rapid Screen Test into U.S. interstate commerce, and refrain from delivering the product for introduction into U.S. interstate commerce, until premarket approval or an IDE for the device has been obtained, and your device otherwise complies fully with the Act.

If you have any questions regarding this matter, you may contact Anna M. Flynn at (240) 402-9156. If you believe that your product is not in violation of the Act, include your reasoning and any supporting information for our consideration. Please be advised that only written communications are considered official.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

Cc: Mr. Andre Han
Vice President, Global Business
JAL Innovation (Singapore) Pte. Ltd.
50 Raffles Place
Level 30
Singapore Land Tower
Singapore 048623