



May 18, 2017

UPS EXPRESS MAIL

To the Registrant of www.americanpumpkins.com
c/o Domains By Proxy, LLC
14455 N. Hayden Road
Scottsdale, Arizona 85260

To Whom It May Concern:

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.americanpumpkins.com>. Your website promotes the In Home Blood Test for HIV 1 and 2 and the Oral In Home Saliva Test for HIV 1 and 2. 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.

These devices promoted on your Internet website are not approved for sale in the United States and have not received investigational device exemptions from premarket approval. The Internet website above does not exclude the sale of the HIV test kits in the United States. Instead, your website appears to promote the In Home Blood Test for HIV 1 and 2 and the Oral In Home Saliva Test for HIV 1 and 2 to buyers in the United States. For example, your website sells the devices 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 products within the United States.

The introduction, or delivery for introduction, of the In Home Blood Test for HIV 1 and 2 or the Oral In Home Saliva Test for HIV 1 and 2 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 your statement about the In Home Blood Test for HIV 1 and 2, which specifically states, “Same test doctors have relied on for years.”

You should take prompt action to correct the violations referenced above. To avoid violating the Act, you must refrain from introducing the In Home Blood Test for HIV 1 and 2 and the Oral In Home Saliva Test for HIV 1 and 2 into U.S. interstate commerce, and refrain from delivering the products for introduction into U.S. interstate commerce, until premarket approvals or IDEs for the devices have been obtained, and your devices otherwise comply fully with the Act.

If you have any questions regarding this matter, you may contact Anna M. Flynn at (240) 402-9156. 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