Zizion Group LLC 3/12/15

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
Silver Spring, MD 20993

WARNING LETTER

MAR 12, 2015

CBER-15-01

UPS EXPRESS MAIL

Mr. Bruce Bertman
Zizion Group LLC.
141 BW 20th Street Suite F5
Boca Raton FL, 33431

Dear Mr. Bertman:

The Food and Drug Administration (FDA) has reviewed your Internet website http://yesprpkit.com. Your website states that your Yes PRP Kit is an ""Easy and accurate PRP-Kit" for medical staffs." Copies of the pertinent Internet website pages are enclosed for your reference.

The Yes PRP Kit is a medical device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) in part because it is intended for use in the cure, mitigation, or treatment of disease. Your website describes the device as a kit for extracting blood from a patient, and preparing from that blood platelet rich plasma for re administration as a treatment for a number of conditions. Your device has an intended use similar to the intended use of previously cleared PRP devices

under 510(k) premarket notification. The law requires that manufacturers of medical devices obtain marketing approval or clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that medical devices are safe and effective or substantially equivalent to other devices already legally marketed in the United States.

(b)(4)

A review of our databases disclosed that your firm has not obtained premarket approval or clearance for these Kit in the United States and has not received an investigational device exemption from premarket approval for these Kit either. Nevertheless, the Internet website above offers the Yes PRP Kit for sale to buyers in the United States. For example, the United States is included in the "drop-down" box on the contact page, inviting orders for shipment of the product within the United States. We also note that you include the FDA logo on your description of the product (linked to the phrase "in progress" in very small letters), which misleads the reader into concluding that your product is legally marketed in the United States. Because you do not have marketing approval or clearance from FDA, marketing these products in the United States is in violation of the law.

These devices are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. 351(f)(1)(B), because you do not have an approved application for premarket approval in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e (a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. 360j (g). Additionally, the devices are misbranded under section 502(o) the Act, 21 U.S.C. 352(o), because notice or other information respecting the device was not provided to FDA, as required by section 510(k) of the Act, 21 U.S.C. 360(k).

You should take prompt action to correct the violations addressed in this letter. Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Your reply should be sent to the Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality, 10903 New Hampshire Avenue, Silver Spring, MD 20993. If you have any questions regarding

this matter, you may contact Najma Khan at (240) 402-9156. Please be advised that only written communications are considered official.

Sincerely,
/S/
Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

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Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

Contact FDA