JANUARY 26, 2018

UPS EXPRESS MAIL

Douglas Ginter, President and CEO
Physicians Products, Inc.
(b) (6)

Dear Mr. Ginter:

The Food and Drug Administration (FDA) has reviewed your Internet website https://www.prpkits.com/. On your website, you offer your product, the Sterile PRP Separation Kit, for sale. Copies of the pertinent Internet website pages are enclosed for your reference.

Your Sterile PRP Separation Kit, whether used with or without the centrifuge you also offer for sale on your website, is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) in part because it is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body of man or other animals (21 U.S.C. § 321(h)).

Your Internet website describes the Sterile PRP Separation Kit as a kit that is "Safe and Sterilized," achieves "7-9 folds High Enrichment" and "helps repair damaged/injured tissues present in the body." The website indicates that the product may be used for a variety of purposes, including plastic surgery, wound care, and hair loss, as well as various dermatological, orthopedic, and veterinary uses.

Your Internet website makes claims such as:

- "PRP kit can extract high concentration of PRP containing more than 1,500,000/µl platelets from 15ml of blood."
- "Our PRP kit produces 1,200,000 – 2,000,000 platelets per micro liter. That is twice, compared to other brands!"
- "The main objective of this Sterile PRP Separation Kit is to attack the point of injury promptly and release growth factors, attract stem cells and support better healing."
- "It has been proven and tested that using our Sterile PRP Separation Kit, a quick, effortless and painless treatment is possible, with little or zero risk for any allergic reactions."
- "The PRP Kit suitably intensifies the healing abilities of the body without having to take the route of surgery or drug medication."

The Act requires that manufacturers of devices that are not exempt obtain marketing approval or clearance for their products from FDA before they may offer them for sale in the United States. This promotes the public health by helping to ensure that devices are safe and effective.

A review of our databases found that your firm has not obtained premarket approval or clearance for the Sterile PRP Separation Kit, and you have not received an investigational device exemption from premarket approval. Nevertheless, on your website, you market the product as "FDA approved" and offer it for sale in U.S. dollars to buyers throughout the United States. Because you do not have marketing approval or clearance from FDA for the Sterile PRP Separation Kit used with or without the centrifuge, marketing this product in the United States appears to be in violation of the Act.

For the above reasons, the Sterile PRP Separation Kit whether sold with or without the centrifuge appears to be 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 (PMA) 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 (IDE) under section 520(g) of the Act, 21 U.S.C. 360j(g). Additionally, the same device appears to be 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).

If you have any questions regarding this matter, you may contact Robert McElwain, Consumer Safety Officer, Division of Case Management, Office of Compliance and Biologics Quality at (240) 402-9015. 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: Douglas Ginter, President and CEO
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