DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

UPS EXPRESS MAIL

Ms. Mary Rogers, President
Dr. PRP America LLC
5330 Carroll Canyon Road, Suite 230
San Diego, California 92121

Dear Ms. Rogers:

The Food and Drug Administration (FDA) has reviewed your Internet website http://drprpamerica.com on November 2, 2016. Your website states that your product, the Dr. PRP Kit, is a "medical device exclusively designed for PRP separation." Copies of the pertinent Internet website pages are enclosed for your reference.

The Dr. PRP Kit whether used with or without the centrifuge you also offer for sale on your website (PRP Centrifuge) 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 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 Dr. PRP Kit as a kit that "delivers highly concentrated PRP from a patient['s] own blood," which the website indicates may be used for a variety of purposes, including treatment of musculoskeletal injuries and tissue regeneration and rejuvenation. Your Internet website makes claims such as:

- "Normal baseline concentration levels for blood platelets hovers around 6%, however PRP technology concentrates platelet levels to around 94% with the use of a centrifuge."
- "[The] PRP Kit contains tools for concentrating and extracting blood platelets and adjusting blood plasma levels."
- The Dr. PRP Kit "aids in the acceleration of our body's natural healing process to solve the various medical challenges patients face today."
- "[A] kit for separating plasma and enriching it with high concentrations of platelets."
- "We are committed to providing the American Healthcare System and in particular, the Cell Therapy Industry with the distribution of regenerative medicine bio devices."
- "These bio devices are developed for use in Platelet-Rich Plasma and Stem Cell procedures."

The Act requires that manufacturers of medical devices obtain marketing approval or clearance for their products from FDA before they may offer them for sale in the United States. 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.

A review of our databases found that your firm has not obtained premarket approval or clearance for the Dr. PRP Kit used with or without the PRP Centrifuge, and you have not received an investigational device exemption from premarket approval. Nevertheless, the website above offers the Dr. PRP Kit and PRP Centrifuge for sale to buyers in the United States. For example, the order form has entry lines for the "state" which indicates the kit is available for United States customers. Also, the pricing for the Dr. PRP Kit and PRP Centrifuge is in U.S. dollars. Because you do not have marketing approval or clearance from FDA for the Dr. PRP Kit used with or without the PRP Centrifuge, marketing this product in the United States appears to be in violation of the Act.

For the above reasons, the Dr. PRP Kit whether sold with or without the PRP 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 Lisa Andersen, Consumer Safety Officer, Division of Case Management, Office of Compliance and Biologics Quality at (240) 402-6207. 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