With increased utilization of platelet-rich plasma (PRP), it is important for clinicians to understand the United States, the Food and Drug Administration (FDA) regulatory role and stance on PRP. Blood products such as PRP fall under the prevue of FDA's Center for Biologics Evaluation and Research (CBER). CBER is responsible for regulating human cells, tissues, and cellular and tissue-based products. The regulatory process for these products is described in the FDA's 21 CFR 1271 of the Code of Regulations. Under these regulations, certain products including blood products such as PRP are exempt and therefore do not follow the FDA's traditional regulatory pathway that includes animal studies and clinical trials. The 510(k) application is the pathway used to bring PRP preparation systems to the market. The 510(k) application allows devices that are "substantially equivalent" to a currently marketed device to come to the market. There are numerous PRP preparation systems on the market today with FDA clearance; however, nearly all of these systems have 510(k) clearance for producing platelet-rich preparations intended to be used to mix with bone graft materials to enhance bone graft handling properties in orthopedic practices. The use of PRP outside this setting, for example, an office injection, would be considered "off
label." Clinicians are free to use a product off-label as long as certain responsibilities are met. Per CBER, when the intent is the practice of medicine, clinicians "have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects." Finally, despite PRP being exempted, the language in 21 CFR 1271 has caused some recent concern over activated PRP; however to date, the FDA has not attempted to regulate activated PRP. Clinicians using activated PRP should be mindful of these concerns and continued to stay informed.