

Is cosmetic platelet-rich plasma a drug to be regulated by the Food and Drug Administration?

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Summary

In the area of cosmetic dermatology, some physicians have been injecting activated platelet-rich plasma into the face to promote cosmesis or using it to enhance fat grafts.

However, subtle changes to the federal drug code (21 CFR 1271.1) made in 2004, when applied to activated PRP, purport to make this autologous substance a federally regulated drug requiring an extensive and costly Biologics License Application. Are autologous cells drugs? Many physicians believe there are significant problems with this regulatory paradigm.

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