

FDA cites 'Significant deviations' at florida stem cell clinic

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(HealthDay)—A Florida stem cell clinic has received a warning letter

from the U.S. Food and Drug Administration about what the agency describes as serious problems that could pose health risks to patients.

The agency said Monday that it has cited U.S. Stem Cell Clinic, of Sunrise, for marketing stem cell products without FDA approval and for "significant deviations from current good manufacturing practice requirements," including some that could affect the "sterility of their products, putting patients at risk."

The FDA said it hasn't approved any biological products made by U.S. Stem Cell Clinic for any use.

"Stem cell clinics that mislead vulnerable patients into believing they are being given safe, effective treatments that are in full compliance with the law are dangerously exploiting consumers and putting their health at risk," FDA Commissioner Scott Gottlieb, M.D., said in an agency news release. "As the FDA takes new steps to advance an efficient, modern approach to the regulation of cell-based regenerative medicine, at the same time we will be stepping up our enforcement actions against clinics that abuse the trust of patients and, more important, endanger their health with unsanitary conditions or by purporting to have treatments which may not provide any benefit."

More information: [More Information](#)

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