

FDA cracking down on fat-melting injections

April 7 2010, By MATTHEW PERRONE , AP Business Writer

(AP) -- The Food and Drug Administration is cracking down on fat-melting injections used in spas across the U.S., saying the drugs have not been proven safe or effective.

Lipodissolve injections, a popular nonsurgical alternative to liposuction, are used to dissolve small fat deposits around the legs, arms and belly. The FDA said Wednesday the drugs have not been cleared by federal scientists, as required by law.

The agency issued warning letters to a half-dozen spas that offer the injections, citing them for making unsubstantiated claims about lipodissolve therapy.

"The claims made for your lipodissolve products are false and misleading in that they are not supported by substantial evidence or substantial clinical experience," states a letter to All About You Medspa in Madison, Ind.

Other spas cited by the FDA included: Pure Med Spa of Boca Raton, Fla., Monarch Med Spa of King of Prussia, Pa., and three others.

The Web site for Monarch Med Spa claims that, "Rather than go through the pain and discomfort associated with liposuction, patients now have the option of a series of injections with very minimal discomfort."

Calls to Monarch Med Spa were not immediately returned midday Wednesday.

FDA regulators called on the spas to stop using such claims and notify the agency within 15 working days of steps they are taking to correct the violations.

Spas that offer the injections say they are safe and effective. But safety advocates have called for proof and urge patients to think twice before paying thousands of dollars for an unproven procedure.

Some patients have complained of swelling, hard lumps and dark spots on their skin after receiving the therapy.

Lipodissolve and similar treatments use two chemicals, phosphatidylcholine, or PC, and sodium dioxycholate, or DC. Injections with the PC/DC mix aren't a treatment for obesity but a way to dissolve deposits of fat in certain areas.

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