Don't believe the hype on 'vaginal rejuvenation,' FDA says

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(HealthDay)—Despite their growing popularity, there's no evidence that

so-called "vaginal rejuvenation" procedures are either safe or effective, the U.S. Food and Drug Administration warns.

The procedures, which use lasers and other energy-based devices to remove or reshape vaginal tissue, claim to treat conditions and symptoms related to menopause, urinary incontinence or sexual function.

But in a statement released Monday, the FDA said it's identified numerous cases of vaginal burns or scarring tied to vaginal rejuvenation, as well as post-procedural pain during sexual intercourse or recurring or chronic pain.

It's true that the agency has "cleared or approved laser and energy-based devices for the treatment of serious conditions like the destruction of abnormal or precancerous cervical or vaginal tissue," or genital warts, FDA Commissioner Dr. Scott Gottlieb noted in the statement.

"But the safety and effectiveness of these devices hasn't been evaluated or confirmed by the FDA for 'vaginal rejuvenation,' " he added.

"In addition to the deceptive health claims being made with respect to these uses, the 'vaginal rejuvenation' procedures have serious risks," Gottlieb said.

In some cases, women who've gone into early menopause after breast cancer treatments are opting for these interventions, but "the deceptive marketing of a dangerous procedure with no proven benefit, including to women who've been treated for cancer, is egregious," Gottlieb said.

In fact, the FDA recently notified seven device manufacturers about inappropriate marketing of their devices for "vaginal rejuvenation" procedures, he pointed out. The companies are: Alma Lasers, BTL Aesthetics, BTL Industries, Cynosure, InMode, Sciton and Thermigen.

They were given 30 days to address the FDA's concerns. If they fail to respond in that time, the FDA said it would consider it's next actions, which could include enforcement measures.

"The deceptive marketing of unproven treatments may not only cause injuries but may also keep some patients from accessing appropriate, recognized therapies to treat severe medical conditions," Gottlieb said.

"These products may be particularly appealing to women who may not be candidates for certain FDA-approved treatments to relieve vaginal dryness, and thus are seeking alternative, non-hormonal options," he explained.

"Women considering treatment for vaginal symptoms should speak to their doctor about the potential and known benefits and risks of all available treatment options," he advised.

The FDA will closely monitor reports of problems associated with "vaginal rejuvenation" procedures, and will keep the public informed, Gottlieb said.

He also encouraged women who've suffered problems after such procedures to report them to the FDA's MedWatch program.

More information: The American Academy of Family Physicians has more on genital problems in women.