FDA approves Intarosa for post-menopausal pain during sex

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SILVER SPRING, Md. — The Food and Drug Administration on Thursday announced its approval of Quebec-based EndoCeutics's Intarosa, a treatment for postmenopausal women experiencing pain during sex, a condition known as dyspareunia and a symptom of vulvar and vaginal atrophy. The condition is the result of a decline in estrogen levels that occurs during menopause.

"Pain during sexual intercourse is one of the most frequent symptoms of VVA reported by postmenopausal women," said Dr. Audrey Gassman, deputy director of the Division of Bone, Reproductive, and Urologic Products in the Office of Drug Evaluation III in the FDA's Center for Drug Evaluation and Research. "Intrarosa provides an additional treatment option for women seeking relief of dyspareunia caused by VVA."

Intarose, a once-daily vaginal insert — is the first approved product to contain prasterone, also known as dehydroepiandrosterone as the active ingredient. The FDA noted that although DHEA is included in some dietary supplements, those products's efficacy and safety have not been established for diagnosing, curing, mitigating, treating or preventing any disease.