FDA Approves Postmenopausal Dyspareunia Treatment

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The FDA today approved Endoceutics' prasterone (Intrarosa), a once-daily vaginal insert for the treatment of women who experience moderate to severe pain during sexual intercourse (dyspareunia) as a result of menopause.

During menopause, vaginal tissues can experience a decline in estrogen levels, leading to a condition known as vulvar and vaginal atrophy (VVA), of which dyspareunia is a common symptom.

The efficacy of Intrarosa was evaluated in a total of 406 healthy postmenopausal women, aged 40 to 80 years, across 2 placebo-controlled studies. After 12 weeks, the use of Intrarosa was associated with reduced pain compared with placebo.

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

In addition, the drug's safety was established in 4 placebo-controlled trials and a 52-week open-label study. The most common adverse reactions reported by patients treated with Intrarosa included vaginal discharge and abnormal Pap smear.

With this approval, Intrarosa is now the first and only product containing prasterone, also known as dehydroepiandrosterone (DHEA), to receive the FDA's nod. Although DHEA is included is some dietary supplements, the efficacy and safety of these products have yet to be established for medicinal purposes.