

**Society for Obstetric Anesthesia and Perinatology (SOAP) Commentary
on the U.S. Food and Drug Administration (FDA) approval
of Dsuvia™ for the management of acute pain**

The Anesthetic and Analgesic Drug Products Advisory Committee of the U.S. Food and Drug Administration (FDA) convened on October 12th 2018 and recommended the approval of Dsuvia™ for the management of moderate-to-severe acute pain in medically supervised settings for adult patients; Dsuvia™ was approved by the U.S. FDA on November 2nd 2018. (1)

Data from two randomized, placebo-controlled studies with a total of 261 patients and two open-label, single-arm studies with a total of 216 patients reported that Dsuvia™ was well-tolerated and showed efficacy across a range of patients as a non-invasive analgesic for the management of moderate-to-severe acute pain. There were no obstetric patients included in these trials.

Dsuvia™ is a 30 mcg sufentanil tablet in a pre-filled applicator for sublingual administration by a healthcare professional. Because of the potential for life-threatening respiratory depression due to accidental exposure, Dsuvia™ is available only through a restricted program called the Dsuvia™ REMS* Program. Dsuvia should only be administered by a healthcare provider in a certified medically supervised healthcare setting.

In the absence of studies showing efficacy and safety in pregnant and postpartum women, the Society for Obstetric Anesthesia and Perinatology (SOAP) is not currently recommending the use of Dsuvia™ for the management of acute pain during pregnancy, during labor and delivery, or postpartum, particularly among breastfeeding women.

*Risk Evaluation and Mitigation Strategy (**REMS**)

(1) <https://www.drugs.com/newdrugs/fda-approves-dsuvia-sufentanil-sublingual-severe-pain-4855.html>