Supplemental Approvals

Generic Name (Trade Nameâ€"Company)	**Uses**/Notes
April 12, 2018	
Bupivacaine liposome injectable suspension ***(Exparel—Pacira Pharmaceuticals)*** **FDA approves new use for nerve block pain relief after shoulder surgeries**	FDA approved a new indication for bupivacaine liposome injectable suspension for use as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia following shoulder surgery in adults for 48 to 72 hours following administration. Interscalene brachial plexus nerve block works by anesthetizing the body's nerves nearest the shoulder to help curb pain. The new indication's approval was based on the results of one multicenter clinical study, which demonstrated that the product is safe and effective for use as an interscalene brachial plexus nerve block to provide postsurgical regional analgesia for shoulder surgeries, such as total shoulder arthroplasty and rotator cuff repair. In accordance with recommendations made by an FDA advisory committee in February, the agency has determined that clinical trial data are not sufficient to support the general use of the agent for regional nerve blocks for postsurgical analgesia other than shoulder surgery. As such, the product's updated labeling clearly articulates both the agent's limitations of use as well as the most up-to-date safety and efficacy data associated with this new indication. In 2011, the agent was approved for local administration to provide postsurgical analgesia.

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