

Subject: EMBEDA® Discontinuation on November 15, 2019

The U.S. Food and Drug Administration (FDA) has posted a [notice of discontinuation](#)¹ for an abuse-deterrent opioid analgesic product. EMBEDA® (morphine sulfate and naltrexone hydrochloride) extended-release capsules will be withdrawn from sale on November 15, 2019. According to information provided in the FDA announcement, based on estimates of existing inventories, it is expected to be commercially unavailable by early 2020. At the time of this bulletin's publication, no additional information was available from the manufacturer of EMBEDA, [Pfizer Pharmaceuticals](#), and this notice should be considered as their business decision to withdraw EMBEDA from the marketplace.

Injured workers who are currently prescribed EMBEDA should contact their physician to review their ongoing requirement for pain medication and consider alternatives to EMBEDA.

First approved by the FDA in 2009, EMBEDA is a combination opioid agonist/opioid antagonist product indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.² No generics for EMBEDA are currently available or anticipated.

The Impact

EMBEDA represents a small number of active opioid prescriptions for First Script® injured workers. Account managers and pharmacists will be contacting First Script accounts with targeted impact assessments and recommendations. For more information, please contact your Account Manager or Account Pharmacist.

For additional information about EMBEDA visit: [EMBEDA Medication Guide](#)

¹ U.S. Food and Drug Administration (FDA). FDA Drug Shortages. Current and Resolved Drug Shortages and Discontinuations Reported to FDA. Morphine Sulfate and Naltrexone Hydrochloride (EMBEDA®) Extended-Release Capsules. October 7, 2019. Available at: <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>

² Highlights of Prescribing Information: EMBEDA – Morphine Sulfate and Naltrexone Hydrochloride capsule, extended release. Available at: <http://labeling.pfizer.com/showlabeling.aspx?id=694>