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Sun Pharma would like to inform you of an important development with regards to Drizalma Sprinkle™ (duloxetine) delayed-release capsules.

The FDA and EU regulatory agencies are currently requiring manufacturers to assess nitrosamine impurities for all molecules in the market. Sun Pharma, in compliance with this new requirement, is now assessing the potential for such impurities in Drizalma Sprinkle™. To be prudent, the organization has also elected not to continue manufacturing or distributing the product until the completion of this assessment.

Please note that this distribution hold applies only to Drizalma Sprinkle™, and no other Sun Long-term Care (LTC) products are impacted. In addition, despite the assessment requirement, there is no issue at this time with in-market Drizalma Sprinkle™ product quality or efficacy.

Our patients are at the center of everything we do, and we continue to be dedicated to researching and developing treatments to address their needs. With that said, Sun LTC remains committed to developing and providing a portfolio of alternative-formulation products designed to address the unmet needs of LTC residents who cannot or will not swallow solid medication forms.

Please reach out to our customer service team at 1-800-818-4555, if you need further assistance.

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening and for emergence of suicidal thoughts and behaviors.