

**CENTER FOR DRUG EVALUATION AND  
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*APPLICATION NUMBER:*

**212516Orig1s000**

**MULTI-DISCIPLINE REVIEW**

**Summary Review**

**Office Director**

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**Clinical Review**

**Non-Clinical Review**

**Statistical Review**

**Clinical Pharmacology Review**

NDA/BLA Multi-disciplinary Review and Evaluation NDA 212516  
 Drizalma Sprinkle (Duloxetine Delayed-Release Capsules)

NDA/BLA Multi-Disciplinary Review and Evaluation

Application Type	505(b)(2) New Drug Application (NDA)
Application Number(s)	NDA 212516
Priority or Standard	Standard
Submit Date(s)	September 9, 2018
Received Date(s)	September 9, 2018
PDUFA Goal Date	July 19, 2019
Division/Office	Division of Psychiatry Products/ Office of Drug Evaluation I
Review Completion Date	
Established/Proper Name	Duloxetine Delayed-Release Capsules 20 mg, 30 mg, 40 mg, and 60 mg
(Proposed) Trade Name	Drizalma Sprinkle
Pharmacologic Class	Serotonin (5-HT) and Norepinephrine Reuptake Inhibitor
Code name	
Applicant	Sun Pharma Global FZE
Doseage form	Oral Capsules
Applicant proposed Dosing Regimen	Dosing regimen varies by indication. Starting dose 30 mg/day to 60 mg/day; target dose (b) (4) mg/day to 60 mg/day; maximum dose 120 mg/day
Applicant Proposed Indication(s)/Population(s)	Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Diabetic Peripheral Neuropathic Pain (DPNP), and Chronic Musculoskeletal Pain
Applicant Proposed SNOMED CT Indication Disease Term for each Proposed Indication	370143000 Major depressive disorder (disorder) 21897009 Generalized anxiety disorder (disorder) 193184006 Chronic painful diabetic neuropathy (disorder) 762452003 Chronic musculoskeletal pain (finding)
Recommendation on Regulatory Action	Approval
Recommended Indication(s)/Population(s) (if applicable)	Major Depressive Disorder: Adults Generalized Anxiety: Adults, Elderly, Children and Adolescents (7 to 17 years of age) Diabetic Peripheral Neuropathic Pain: Adults Chronic Musculoskeletal Pain: Adults
Recommended SNOMED CT Indication Disease Term for each Indication (if applicable)	370143000 Major depressive disorder (disorder) 21897009 Generalized anxiety disorder (disorder) 193184006 Chronic painful diabetic neuropathy (disorder) 762452003 Chronic musculoskeletal pain (finding)
Recommended Dosing Regimen	Dosing regimen varies by indication. Starting dose 30 mg/day to 60 mg/day; target dose (b) (4) mg/day to 60 mg/day; maximum dose 120 mg/day

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