

New Suitability Petitions

June 2024



ABOUT

This report identifies new suitability petition. Information used for analyses is sourced from:

1. Upcoming suitability petitions studied from filing documents.
2. Approved product details from GenUS – Research Delta Advisors.
3. Labels of existing drugs approved by regulatory agencies like USFDA

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr.	Company	Application Status	Date	Generic Name	Name & App. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
1	Hyman, Phelps & McNamara, P.C.	Filed	06-Jun-24	BUPIVACAINE HYDROCHLORIDE	MARCAINE HCL (016964)	Injectable	10ml,30ml	Strength	100ml,500ml, 1L,2L	Link
2	Premium Content	Filed	06-Jun-24	FENTANYL CITRATE	Premium Content					
3		Filed	06-Jun-24	OXYTOCIN						
4		Filed	06-Jun-24	ROPIVACAINE HYDROCHLORIDE						
5		Filed	07-Jun-24	CHLORZOAZONE						
6		Filed	10-Jun-24	DICLOFENAC POTASSIUM						

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr.	Company	Application Status	Date	Generic Name	Name & App. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
7	Premium Content	Filed	17-Jun-24	OLAPARIB	Premium Content					
8		Filed	17-Jun-24	BUPRENORPHINE HYDROCHLORIDE						
9		Filed	19-Jun-24	ROSUVASTATIN CALCIUM						
10		Withdrawal	13-Jun-24	VIGABATRIN						

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