

New Suitability Petitions

30th October 2024

October 2024



ABOUT

This report identifies new Suitability Petitions Filed, Accepted/Denied and Approved/Withdrawn. 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 Petitions Filed

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Application Status	Date	Generic Name	Name & App. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
1	Pharmobedient Consulting LLC	Filed	01-Oct-24	CYPROHEPTADINE HYDROCHLORIDE	PERIACTIN (012649)	Tablet	4mg	Strength	2mg	Link
2	[Redacted]	Filed	02-Oct-24	PIROXICAM	Premium Content					
3		Filed	02-Oct-24	PIROXICAM						

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Application Status	Date	Generic Name	Name & App. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
4	[Redacted]	Filed	08-Oct-24	NELARABINE	Premium Content					
5		Filed	10-Oct-24	TOPIRAMATE						
6		Filed	18-Oct-24	APIXABAN						

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Application Status	Date	Generic Name	Name & App. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
7	[Redacted]	Filed	22-Oct-24	CARBINOXAMINE MALEATE	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
8		Filed	22-Oct-24	CYCLOBENZAPRI NE HYDROCHLORIDE						
9		Filed	22-Oct-24	CYCLOBENZAPRI NE HYDROCHLORIDE						

Premium Content

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Sr. No.	Company	Application Status	Date	Generic Name	Name & App. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
10	[Redacted]	Filed	22-Oct-24	METHIMAZOLE	Premium Content					
11		Filed	24-Oct-24	BENAZEPRIL HYDROCHLORIDE; HYDROCHLOROT HIAZIDE						
12		Filed	24-Oct-24	BENAZEPRIL HYDROCHLORIDE						

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Application Status	Date	Generic Name	Name & App. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
13	[Redacted]	Filed	23-Oct-24	HYDROCHLOROT HIAZIDE	Premium Content					
14		Filed	24-Oct-24	PIROXICAM						

Suitability Petitions Accepted/Denied

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Application Status	Date	Generic Name	Name & App. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
1	Pharmobedient Consulting LLC	Denied	01-Oct-24	DANTROLENE SODIUM	DANTRIUM (017443)	Capsule	25,50,100mg	Dosage	Orally Disintegrating Tablet	Link
2	[Redacted]	Accepted	15-Oct-24	CETRORELIX ACETATE	Premium Content					
3		Accepted	21-Oct-24	AMANTADINE HYDROCHLORIDE						

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Sr. No.	Company	Application Status	Date	Generic Name	Name & App. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
4		Accepted	24-Oct-24	NEOSTIGMINE METHYLSULFAT	Premium Content					
5		Denied	24-Oct-24	NEOSTIGMINE METHYLSULFAT						

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Application Status	Date	Generic Name	Name & App. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
6	[Redacted]	Denied	25-Oct-24	LEVETIRACETAM	Premium Content					
7		Accepted	21-Oct-24	LACOSAMIDE						
8		Denied	22-Oct-24	BUSPIRONE HYDROCHLORID E						

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Application Status	Date	Generic Name	Name & App. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
9	[Redacted]	Accepted	22-Oct-24	BUSPIRONE HYDROCHLORIDE	[Redacted]					
10		Accepted	16-Oct-24	ESCITALOPRAM OXALATE						
11		Accepted	16-Oct-24	ESCITALOPRAM OXALATE						
12		Accepted	18-Oct-24	OLAPARIB						

Premium Content

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Application Status	Date	Generic Name	Name & App. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
13		Accepted	16-Oct-24	BUPRENORPHIN E HYDROCHLORID E	Premium Content					

Suitability Petitions Approved/Withdrawn

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Application Status	Date	Generic Name	Name & App. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
1	[Redacted]	Withdrawn	18-Oct-24	DICLOFENAC POTASSIUM	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
2		Final Approval	19-Sep-24	HYDROCHLOROT HIAZIDE						
3		Tentative Approval	02-Oct-24	NILOTINIB HYDROCHLORIDE						
4		Final Approval	24-Oct-24	BACLOFEN						

Premium Content

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