New Suitability Petitions

7th January 2025

December 2024

RESEARCH DELTA

New Suitability Petition (Dec - 2024)

ABOUT

This report identifies new Suitability Petitions Filed, Accepted/Denied and Approved/Withdrawn.

A suitability petition is a request by an ANDA sponsor (called the "petitioner") to submit an ANDA for a proposed generic drug that differs from the reference listed drug (RLD). Certain differences between a reference listed drug (RLD) and a proposed generic drug product may be permitted in an ANDA if these differences are the subject of an approved suitability petition submitted under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act.

Under GDUFA III, the FDA commits to addressing Suitability Petition issues. The commitment involves assigning goal dates, actively reviewing a percentage within specified time frames, and prioritizing critical concerns like drug shortages, public health emergencies, waste reduction, or special reviews.

Information used for analysis 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

New Suitability Petition (Dec - 2024)

Suitability Petitions Filed

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Appl Status	Date	Generic Name	Name & Appl. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
1.	Rising Pharma	Filed	13-Dec-2024	Dicyclomine Hydrochloride	BENTYL 007409	Capsules	10 mg	Strength	20 and 40 mg	Link
2.		Filed	16-Dec-2024	Warfarin Sodium	Premium Content					

New Suitability Petition (Dec - 2024)

Suitability Petitions Accepted/Denied

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Appl Status	Date	Generic Name	Name & Appl. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
1.		Denied	11-Dec-2024	Oxytocin						
2.		Denied	10-Dec-2024	Oxytocin						
3.		Accepted	10-Dec-2024	Ropivacaine Hydrochloride						

Premium Content

New Suitability Petition (Dec - 2024)

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Appl Status	Date	Generic Name	Name & Appl. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
					Premium Content					
4.		Denied	23-Dec-2024	Chlorzoxazone						
5.		Denied	20-Dec-2024	Rosuvastatin Calcium						

New Suitability Petition (Dec - 2024)

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Appl Status	Date	Generic Name	Name & Appl. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
6.		Denied	11-Dec-2024	Eslicarbazepine Acetate	Premium Content					
7.		Accepted	26-Dec-2024	Lacosamide						
8.		Accepted	26-Dec-2024	Amlodipine and Benazepril Hydrochloride						
9.		Accepted	16-Dec-2024	Pimavanserin						
10.		Denied	03-Dec-2024	Cisatracurium Besylate						

New Suitability Petition (Dec - 2024)

Suitability Petitions Approved/Withdrawn

Suitability Petitioner Information					RLD Information			Suitability Petition Product Information		
Sr. No.	Company	Appl Status	Date	Generic Name	Name & Appl. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
1.		Withdrawn	12-Dec-2024	Vancomycin Hydrochloride	Premium Content					
2.		Approval	11-Dec-2024	Solriamfetol Hydrochloride						
3.		Approval	19-Dec-2024	Carbinoxamine Maleate						
4.		Approval	20-Dec-2024	Gabapentin						

New Suitability Petition (Dec - 2024)

Research Delta Advisors

G4 Sani Apt., Subhanpura,
Vadodara, Gujarat,
India - 390 023, Tel: +91.9909919584
nimish@researchdelta.com