New Suitability Petitions

4th October 2025

September 2025

RESEARCH DELTA

New Suitability Petition (Sept - 2025)

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This report identifies new Suitability Petitions Filed, Accepted/Denied and Approved/Withdrawn.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 (Sept - 2025)

Suitability Petitions Filed

Suitability Petitioner Information					RLD/RS 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.	BPI Labs	Filed	04-Sept-25	Mycophenolate Mofetil	CellCept 050758	Injectable	500 mg/vial	Strength	1 g/vial and 1.5 g/vial	Link
2.			04-Sept-25	Ubrogepant	Premium Content					
3.			04-Sept-25	Ketamine Hydrochloride						
4.			05-Sept-25	Sertraline Hydrochloride						
5.			11-Sept-25	Methenamine Hippurate						

New Suitability Petition (Sept - 2025)

Suitability Petitioner Information					RLD/RS 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.			19-Sept-25	Methimazole	Premium Content					
7.			23-Sept-25	Lactulose						

New Suitability Petition (Sept - 2025)

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.			26-Sept-25	Tizanidine						
2.			22-Sept-25	Cyclobenzaprine Hydrochloride						
3.			25-Sept-25	Linezolid						
4.			26-Sept-25	Indomethacin						
5.			05-Sept-25	Potassium Acetate						

New Suitability Petition (Sept - 2025)

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.			05-Sept-25	Ketorolac Tromethamine	Premium Content					
7.			22-Sept-25	Flurbiprofen						

New Suitability Petition (Sept - 2025)

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.			28-Aug-25	Tizanidine Hydrochloride	Premium Content					

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