New Suitability Petitions

4th November 2025

4th November 2025

RESEARCH DELTA

New Suitability Petition (Oct - 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This report identifies new Suitability Petitions Filed, Accepted/Denied and Approved/Withdrawn.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 (Oct - 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.	Newcastle Bioscience	Reconsideration Petition Filed	24-Oct-25	Rizatriptan Benzoate	Maxalt 020864	Tablets	5 mg and 10 mg	Strength	7.5 mg	Link
2.			15-Oct-25	Lactulose						
3.			08-Oct-25	Diclofenac Sodium						
4.			09-Oct-25	Pyridostigmine Bromide						
5.			09-Oct-25	Buprenorphine Hydrochloride						

New Suitability Petition (Oct - 2025)

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Sr. No.	Company	Appl Status	Date	Generic Name	Name & Appl. No	Dosage	Strengths	Type of Alteration	Proposed Alteration	Doc Link
6.			17-Oct-25	Buprenorphine Hydrochloride; Naloxone Hydrochloride	Premium Content					
7.			16-Oct-25	Probenecid						
8.			16-Oct-25	Enzalutamide						
9.			17-Oct-25	Methylphenidate Hydrochloride						

New Suitability Petition (Oct - 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
10.			20-Oct-25	Flurbiprofen						
11.			20-Oct-25	Liothyronine sodium						
12.			20-Oct-25	Tizanidine						
13.			24-Oct-25	Desloratadine						
14.			31-Oct-25	Heparin Sodium						

New Suitability Petition (Oct - 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.			17-Oct-25	Diclofenac Potassium						
2.			03-Oct-25	Aripiprazole						
3.			15-Oct-25	Hydrocortisone						
4.			14-Oct-25	Testosterone enanthate						
5.			17-Oct-25	Pregabalin						

Premium Content

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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.			03-Oct-25	Calcitriol						
7.			10-Oct-25	Ganirelix Acetate						
8.			31-Oct-25	Indomethacin						
9.			22-Oct-25	Montelukast Sodium						
10.			01-Oct-25	Rizatriptan Benzoate						
11.			23-Oct-25	Paclitaxel						
12.			23-Oct-25	Celecoxib						
13.			01-Oct-25	Abiraterone Acetate						

New Suitability Petition (Oct - 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.			02-Oct-25	Mirtazapine	Premium Content					
2.			06-Oct-25	Buspirone Hydrochloride						

Research Delta Advisors

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