New Suitability Petitions

3rd May 2025

May 2025

RESEARCH DELTA

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This report identifies new Suitability Petitions Filed, Accepted/Denied and Approved/Withdrawn.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

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.	Hyman, Phelps & Mcnamara, P.C.	Filed	30-May-25	Paclitaxel	Abraxane 021660	Powder	100 mg/vial	Strength	200 mg/vial	Link
2.		Filed	30-May-25	Rizatriptan Benzoate						
3.		Filed	30-May-25	Tolmetin						
4.		Filed	30-May-25	Tolmetin						
5.		Filed	22-May-25	Montelukast Sodium						
6.		Filed	16-May-25	Irbesartan						
7.		Filed	16-May-25	Cyproheptadine Hydrochloride						

Premium Content

New Suitability Petition (May - 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
8.		Filed	16-May-25	Flurbiprofen	Premium Content					
9.		Filed	09-May-25	Indomethacin						
10.		Filed	09-May-25	Carbidopa And Levodopa						
11.		Filed	09-May-25	Ganirelix Acetate						
12.		Filed	07-May-25	Calcitriol						
13.		Filed	01-May-25	Ketorolac Tromethamine						
14.		Filed	01-May-25	Pregabalin						

New Suitability Petition (May - 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
15.		Filed	01-May-25	Rivaroxaban	Premium Content					

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.		Accepted	21-May-25	Metronidazole	Premium Content					
2.		Denied	08-May-25	Colestipol Hydrochloride						
3.		Denied	14-May-25	Hydrochlorothiazide						
4.		Denied	28-May-	Triamcinolone Acetonide						

New Suitability Petition (May - 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
			25		Premium Content					
5.		Denied	15-May-25	Warfarin Sodium						
6.		Accepted	14-May-25	Tizanidine						
7.		Accepted	07-May-25	Dicyclomine Hydrochloride						

There are no new Suitability Petitions Approved/Withdrawn this month.

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