New Suitability Petitions

8th May 2025

April 2025

RESEARCH DELTA

New Suitability Petition (Mar - 2025)

RESEARCH DELTA

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This report identifies new Suitability Petitions Filed, Accepted/Denied and Approved/Withdrawn.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 (Mar - 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.	Close Consulting	Filed	01-Apr-25	Linezolid	Zyvox 021130	Tablets	600mg	Dosage	Tablet For Oral Suspension	Link
2.		Filed	18-Apr-25	Potassium Acetate						
3.		Filed	15-Apr-25	Testosterone Enanthate						
4.		Filed	09-Apr-25	Hydrocortisone						
5.		Filed	03-Apr-25	Quetiapine Fumarate						

Premium Content

New Suitability Petition (Mar - 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.		Filed	03-Apr-25	Ceftriaxone	Premium Content					
7.		Filed	03-Apr-25	Spironolactone						
8.		Filed	01-Apr-25	Indomethacin						

New Suitability Petition (Mar - 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.		Denied	22-Apr-25	Ketorolac Tromethamine	Premium Content					
2.		Denied	23-Apr-25	Cyclobenzaprine Hydrochloride						
3.		Denied	22-Apr-25	Benazepril Hydrochloride						
4.		Denied	08-Apr-25	Piroxicam						
5.		Denied	08-Apr-25	Amlodipine Besylate, Hydrochlorothiazide, Valsartan						
6.		Denied	22-Apr-25	Benazepril Hydrochloride and Hydrochlorothiazide						

New Suitability Petition (Mar - 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
7.		Denied	22-Apr-25	Benazepril Hydrochloride						

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.		Tentative Approval	26-Mar-25	Lumateperone Tosylate	Premium Content					
2.		Approval	03-Apr-25	Hydrochlorothiazide						
3.		Approval	25-Mar-25	Dicyclomine Hydrochloride						

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