New Suitability Petitions

2nd Jun 2025

JUN 2025

RESEARCH DELTA

New Suitability Petition (JUN - 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This report identifies new Suitability Petitions Filed, Accepted/Denied and Approved/Withdrawn.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 (JUN - 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.	Senores Pharmaceuticals	Filed	11-Jun-25	Cyproheptadine Hydrochloride	Periactin 013220	Oral Solution	2mg/5ml	Dosage	2 mg and 4 mg Orally Disintegrating Tablets	Link
2.		Filed	03-Jun-25	Montelukast Sodium	Premium Content					
3.		Filed	03-Jun-25	Celecoxib						
4.		Filed	03-Jun-25	Celecoxib						
5.		Filed	09-Jun-25	Abiraterone Acetate						
6.		Filed	12-Jun-25	Tadalafil						

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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
7.		Filed	25-Jun-25	Maribavir	Premium Content					
8.		Filed	17-Jun-25	Tadalafil						
9.		Filed	03-Jun-25	Dexchlorpheniramine Maleate						

New Suitability Petition (JUN - 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.		Accepted	05-Jun-25	Capecitabine	Premium Content					
2.		Accepted	02-Jun-25	Olaparib						
3.		Accepted	02-Jun-25	Ivermectin						
4.		Accepted	11-Jun-25	Meloxicam						
5.		Denied	11-Jun-25	Chlorzoxazone						
6.		Denied	05-Jun-25	Nabumetone						
7.		Accepted	02-Jun-25	Binimetinib						

New Suitability Petition (JUN – 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.		Tentative Approval	11-April-25	Empagliflozin	Premium Content					
2.		Tentative Approval	19-May-25	Lumateperone Tosylate						
3.		Tentative Approval	27-May-25	Lumateperone						
4.		Tentative Approval	01-May-25	Lumateperone Tosylate						

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5.		Final Approval	10-Jun-25	Sodium Polystyrene Sulfonate	Premium Content
6.		Withdrawn	17-Jun-25	Tadalafil	

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