New Suitability Petitions

3rd Aug 2025

Aug 2025

RESEARCH DELTA

New Suitability Petition (Aug - 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This report identifies new Suitability Petitions Filed, Accepted/Denied and Approved/Withdrawn.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 (Aug - 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.	Premier Research	Filed	07-Aug-25	Atorvastatin calcium	Lipitor 020702	10,20,40 and 80 mg	Tablets	Strength	15,30 and 60 mg	Link
2.			22-Aug-25	Ranolazine	Premium Content					
3.			29-Aug-25	Metformin Hydrochloride						

New Suitability Petition (Aug - 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.			05-Aug-25	Oxycodone Hydrochloride and Acetaminophen	Premium Content					
2.			11-Aug-25	Spironolactone						
3.			11-Aug-25	Spironolactone						
4.			11-Aug-25	Ceftriaxone						
5.			28-Aug-25	Quetiapine						

New Suitability Petition (Aug - 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.			11-Aug-25	Tolmetin sodium	Premium Content					
7.			11-Aug-25	Tolmetin sodium						

New Suitability Petition (Aug - 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.			05-Aug-25	Sulindac	Premium Content					
2.			25-Aug-25	Sodium Bicarbonate						

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