New Suitability Petitions

7th March 2025

February 2025

RESEARCH DELTA

New Suitability Petition (Feb - 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This report identifies new Suitability Petitions Filed, Accepted/Denied and Approved/Withdrawn.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 (Feb - 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.	Pharmobedient Consulting	Filed	04-Feb-25	Gabapentin	Neurontin 020235	Capsule	100, 300 and 400 mg	Strength	200 mg	Link
2.		Filed	04-Feb-25	Nabumetone	Premium Content					
3.		Filed	05-Feb-25	Rimegepant						
4.		Filed	07-Feb-25	Gabapentin						
5.		Filed	12-Feb-25	Binimetinib						
6.		Filed	13-Feb-25	Valacyclovir Hydrochloride						
7.		Filed	23-Feb-25	Hydrocortisone						

New Suitability Petition (Feb - 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	13-Feb-25	Leucovorin Calcium	Premium Content					
2.		Accepted	12-Feb-25	Estradiol						
3.		Denied	18-Feb-25	Diclofenac Potassium						
4.		Denied	13-Feb-25	Bisoprolol Fumarate						
5.		Accepted	18-Feb-25	Clonidine Hydrochloride						

New Suitability Petition (Feb - 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.		Accepted	05-Feb-25	Fludrocortisone Acetate	Premium Content					
7.		Accepted	04-Feb-25	Nelarabine						
8.		Denies	26-Feb-25	Apixaban						
9.		Accepted	24-Feb-25	Carbinoxamine Maleate						
10.		Accepted	20-Feb-25	Methimazole						

New Suitability Petition (Feb - 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.		Approved	31-Jan-25	Baclofen	Premium Content					
2.		Approved	06-Feb-25	Fluorouracil						

Research Delta Advisors

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