New Suitability Petitions

6th April 2026

March 2026

RESEARCH DELTA

New Suitability Petition (Mar - 2026)

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This report identifies new Suitability Petitions Filed, Accepted/Denied and Approved/Withdrawn.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.

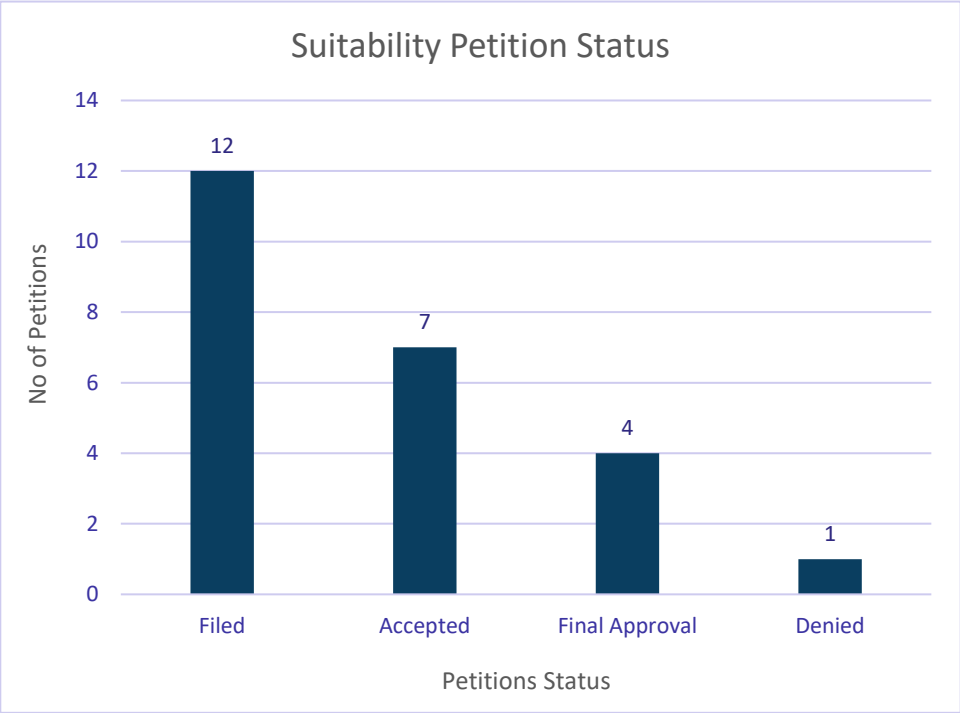
Under GDUFA III, the FDA commits to addressing Suitability Petition issues. The commitment involves assigning goal dates, actively reviewing a percentage within specified time frames, and prioritising critical concerns like drug shortages, public health emergencies, waste reduction, or special reviews.

Information used for analysis is sourced from:

1. Upcoming Suitability Petitions studied from the filing documents.
2. Approved product details from GenUS – Research Delta Advisors.
3. Labels of existing drugs approved by regulatory agencies like the USFDA

New Suitability Petition (Mar – 2026)

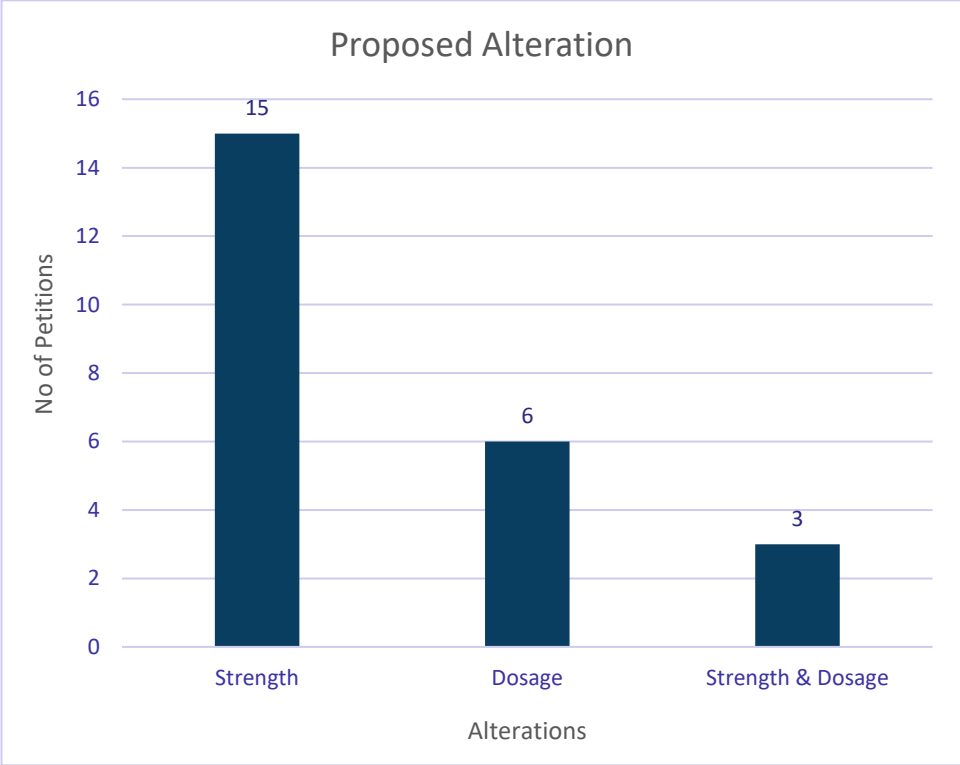
Suitability Petition Volume by Application Outcome



Source – GenUS, Research Delta Advisors

Suitability Petition: Strength Modification Leads the Race

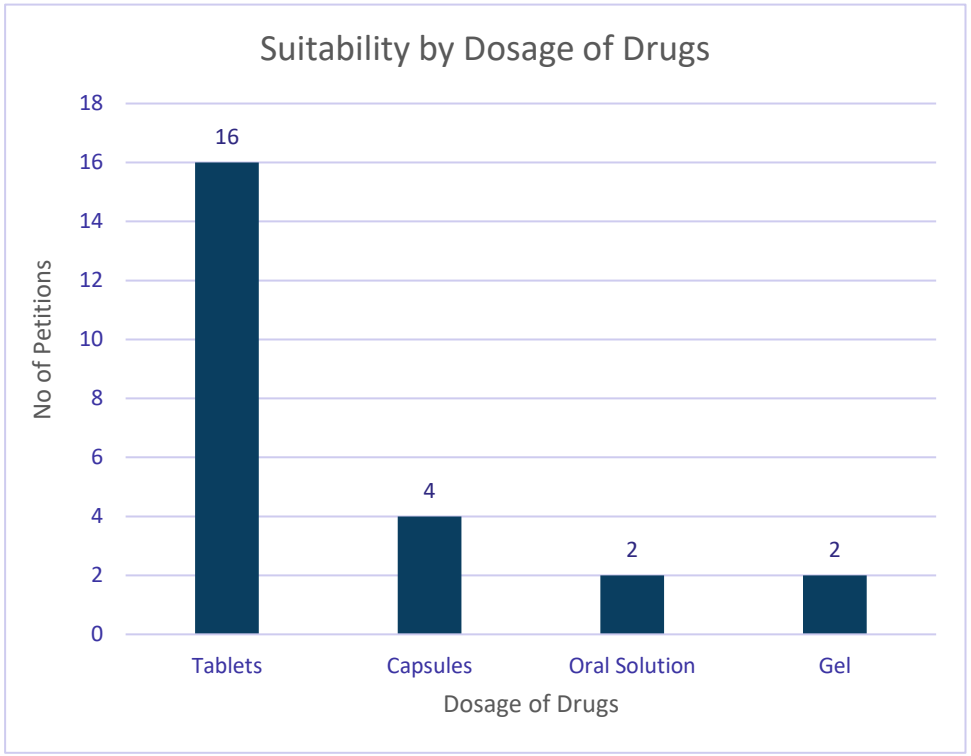
Modifying the strength is the main target of the suitability petition



Source – GenUS, Research Delta Advisors

Suitability Petition Volume by Drug Dosage

An oral drug is the main target of the suitability petition

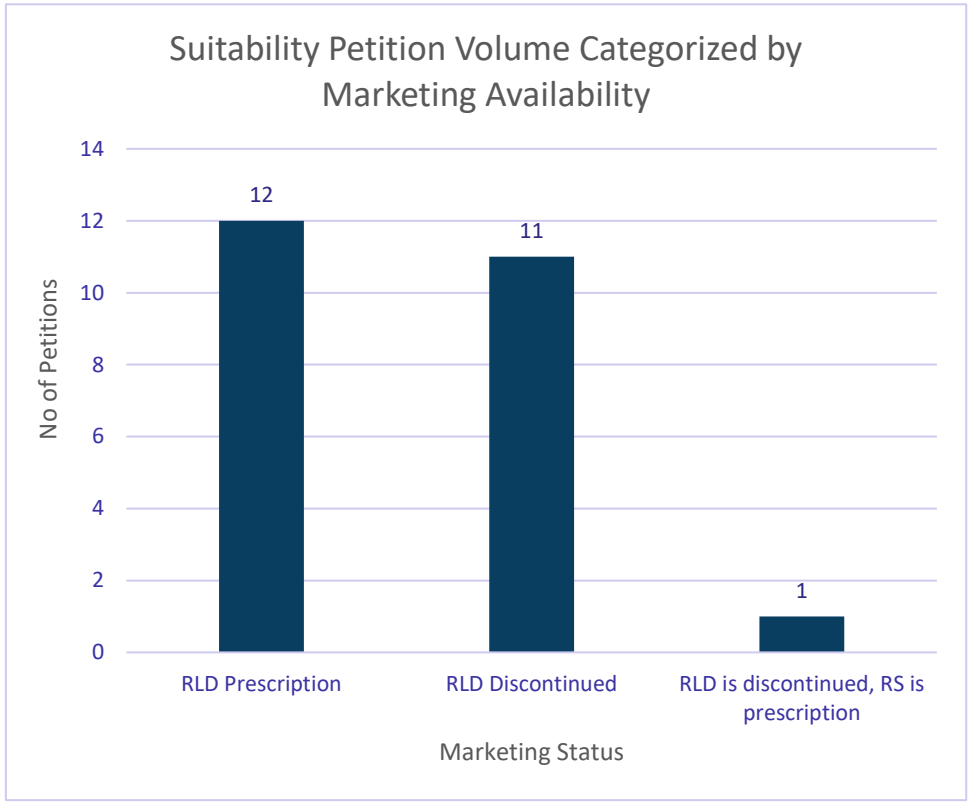


Source – GenUS, Research Delta Advisors

New Suitability Petition (Mar - 2026)

Marketing Status of RLD filed under Suitability Petition

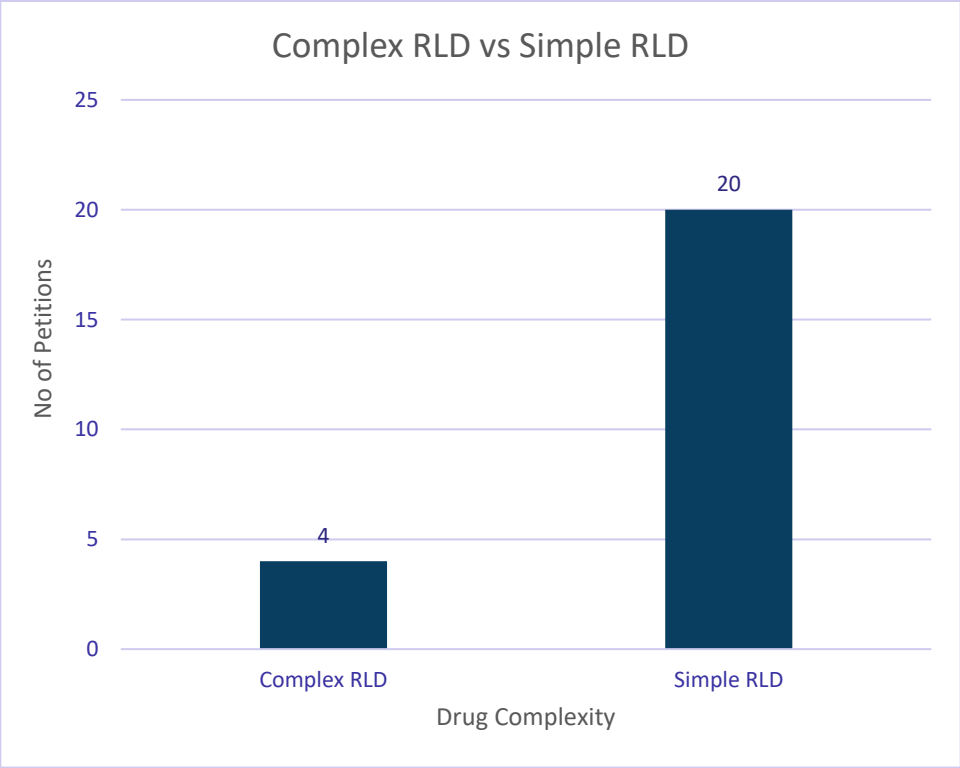
~ 50% of the RLD Products are still available in the market



Source – GenUS, Research Delta Advisors

Suitability Petition Volume Categorized by RLD Complexity

Simple RLD is the main target for the Suitability Petition



Source – GenUS, Research Delta Advisors

New Suitability Petition (Mar - 2026)

Suitability Petitions Filed

Suitability Petitioner Information					RLD/RS 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.	Lachman Consulting	Filed	04-Mar-26	Gabapentin	Neurontin 021129	Oral Solution	250 mg/5 ml	Strength &Dosage	300mg/ sachet, 400mg/ sachet, and 600 mg/sachet; Powder for Oral Solution	Link
2.			04-Mar-26	Estradiol						
3.			05-Mar-26	Buspirone Hydrochloride						
4.			06-Mar-26	Progesterone						
5.			06-Mar-26	Levetiracetam						

New Suitability Petition (Mar - 2026)

Suitability Petitioner Information					RLD/RS 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.			06-Mar-26	Ibuprofen						
7.			09-Mar-26	Pregabalin						
8.			13-Mar-26	Atomoxetine Hydrochloride						

Premium Content

New Suitability Petition (Mar - 2026)

Suitability Petitioner Information					RLD/RS 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
9.			13-Mar-26	Sildenafil	Premium Content					
10.			24-Mar-26	Estrogens, Conjugated						
11.			27-Mar-26	Hydrocortisone						
12.			31-Mar-26	Clomiphene Citrate						

New Suitability Petition (Mar - 2026)

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.			06-Mar-26	Acetaminophen; Oxycodone Hydrochloride						
2.			17-Mar-26	Metformin Hydrochloride						
3.			03-Mar-26	Methimazole						
4.			23-Mar-26	Diclofenac Sodium						
5.			23-Mar-26	Methylphenidate Hydrochloride						
6.			10-Mar-26	Liothyronine Sodium						

New Suitability Petition (Mar - 2026)

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.			30-Mar-26	Tizanidine	Premium Content					
8.			06-Mar-26	Acetaminophen; Oxycodone Hydrochloride						

New Suitability Petition (Mar - 2026)

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.			26-Feb-26	Dapsone	Premium Content					
2.			06-Mar-26	Gabapentin						
3.			10-Mar-26	Oxybutynin Chloride						
4			23-Mar-26	Tramadol Hydrochloride						

New Suitability Petition (Mar – 2026)

Research Delta Advisors

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