

New Suitability Petitions

5th Jun 2026

May 2026



ABOUT

This report identifies new Suitability Petitions Filed, Accepted/Denied and Approved/Withdrawn.

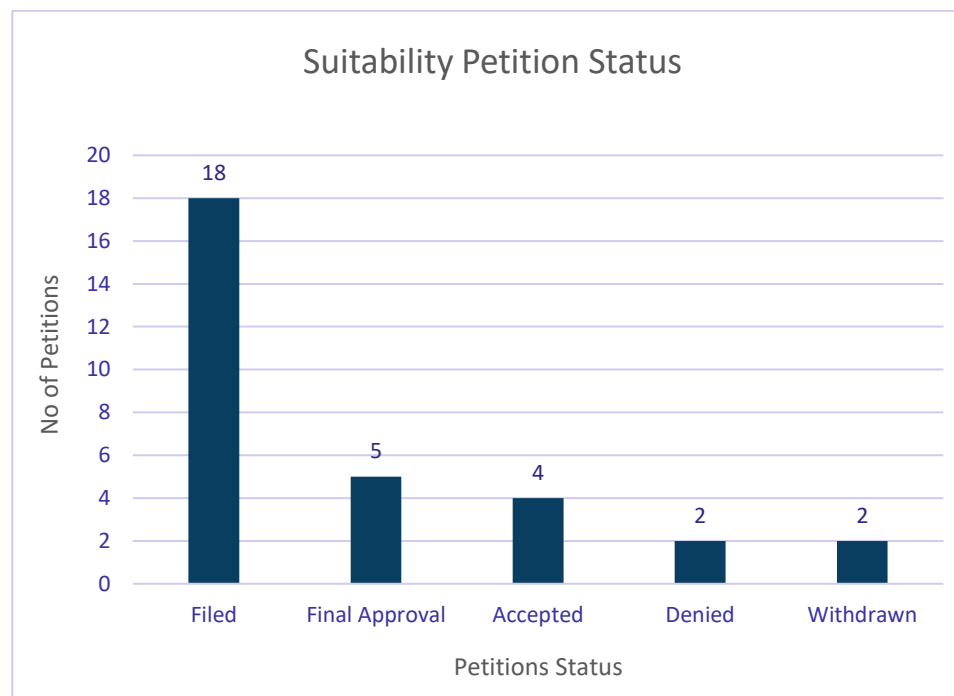
A suitability petition is a request by an ANDA sponsor (called the “petitioner”) to submit an ANDA for a proposed generic drug that differs from the reference listed drug (RLD). Certain differences between a reference listed drug (RLD) and a proposed generic drug product may be permitted in an ANDA if 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

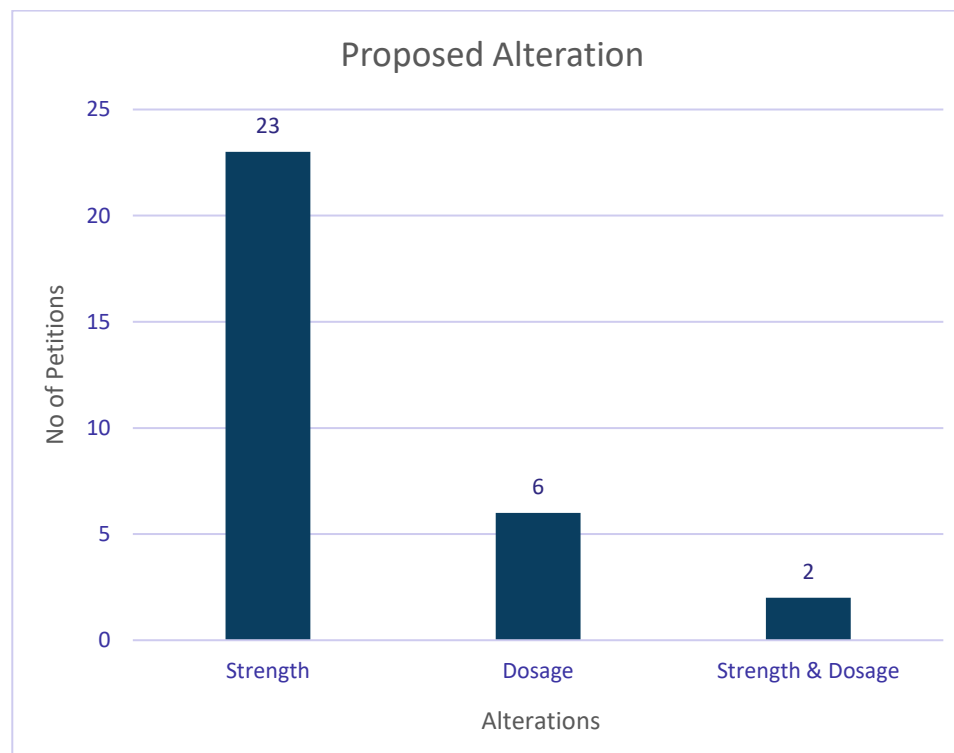
Suitability Petition Volume by Application Outcome



Source – GenUS, Research Delta Advisors

Suitability Petition: Strength Modification Leads the Race

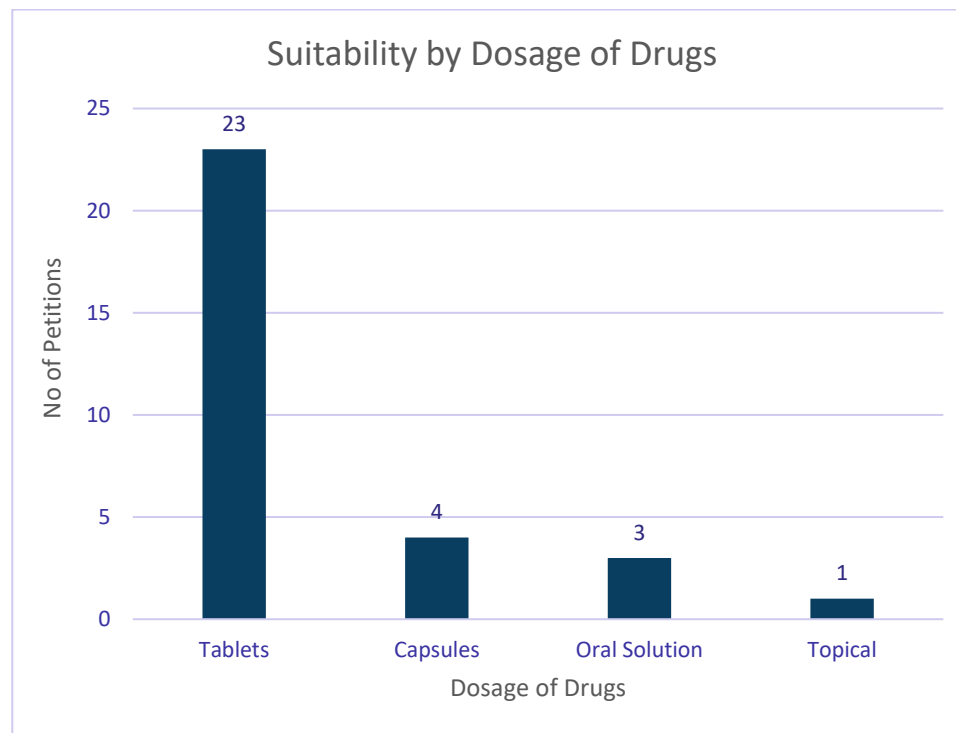
Modifying the strength is the main target of the suitability petition



Source – GenUS, Research Delta Advisors

Suitability Petition Volume by Drug Dosage

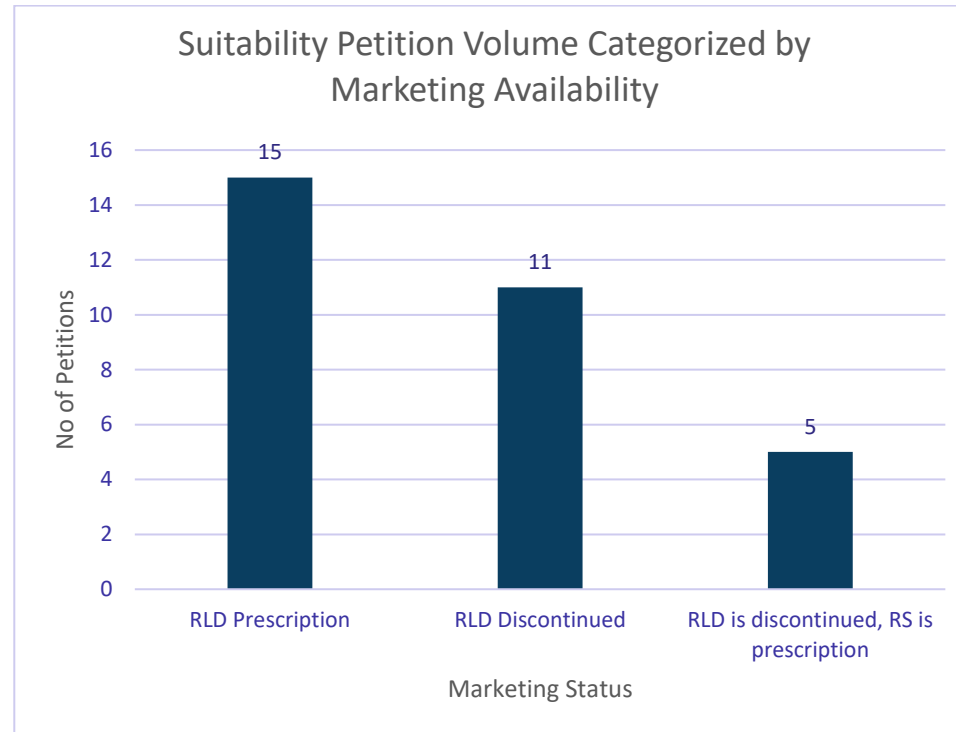
An oral drug is the main target of the suitability petition



Source – GenUS, Research Delta Advisors

Marketing Status of RLD filed under Suitability Petition

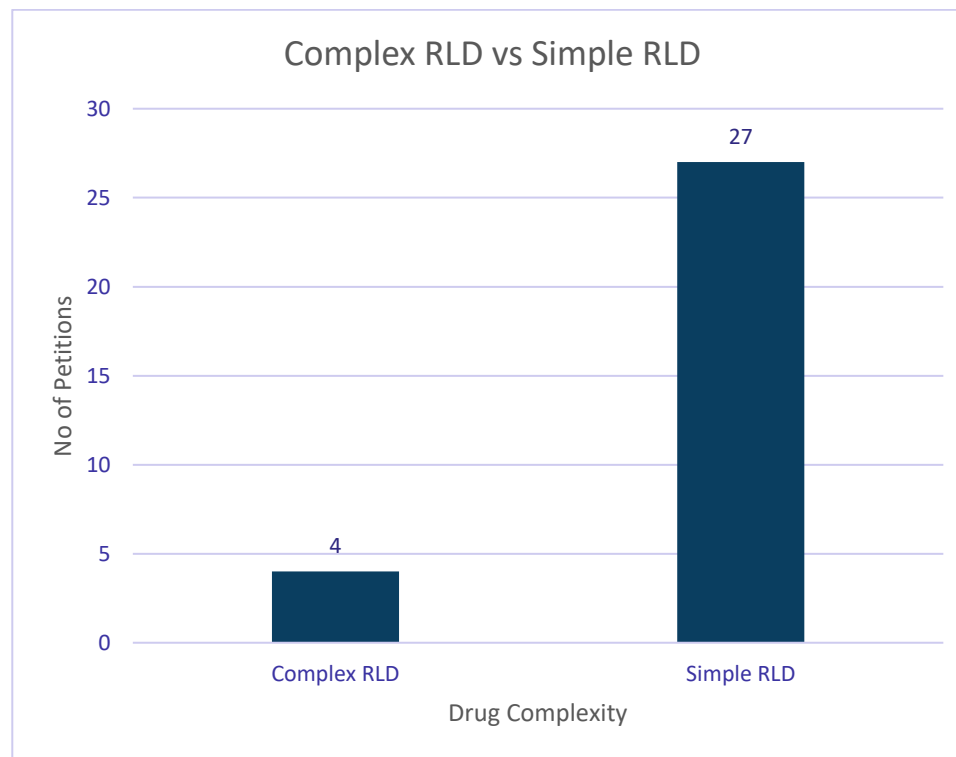
~ 48% of the RLD Products are still available in the market



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 (May - 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.	Appco Pharma	Filed	01-May-26	Acetazolamide	Diamox 008943 A040195 (RS)	Tablets	125 mg and 250 mg	Strength	500 mg	Link
2.	[Redacted]	[Redacted]	04-May-26	Apixaban	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
3.			05-May-26	Trazodone Hydrochloride						
4.			06-May-26	Desloratadine						
5.			08-May-26	Prazosin Hydrochloride						
6.			08-May-26	Gabapentin						

Premium Content

New Suitability Petition (May - 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
7.	[Redacted]	[Redacted]	11-May-26	Naltrexone Hydrochloride	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
8.			14-May-26	Tranexamic Acid						
9.			14-May-26	Gabapentin						
10.			21-May-26	Levetiracetam						
11.			27-May-26	Ibuprofen						
12.			27-May-26	Cyproheptadine Hydrochloride						

Premium Content

New Suitability Petition (May - 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
13.	[Redacted]	[Redacted]	27-May-26	Tramadol Hydrochloride and Acetaminophen	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
14.			27-May-26	Triamcinolone Acetonide						
15.			27-May-26	Metformin Hydrochloride						
16.			28-May-26	Rosuvastatin Calcium						
17.			28-May-26	Ezetimibe And Simvastatin						
18.			28-May-26	Trazodone Hydrochloride						

Premium Content

New Suitability Petition (May - 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.	[Redacted]	[Redacted]	15-May-26	Clemastine Fumarate	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
2.			29-May-26	Clemastine Fumarate						
3.			15-May-26	Dicyclomine Hydrochloride						
4.			22-May-26	Lisinopril Hydrochlorothiazide						

Premium Content

New Suitability Petition (May - 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
5.	[Redacted]	[Redacted]	26-May-26	Benazepril Hydrochloride; Hydrochlorothiazide	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
6.			19-May-26	Dabrafenib Mesylate						

New Suitability Petition (May - 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.	[Redacted]	[Redacted]	11-May-26	Oxycodone Hydrochloride	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
2.			04-May-26	Ivermectin						
3.			13-May-26	Buspirone Hydrochloride						
4.			13-May-26	Cyclobenzaprine Hydrochloride						
5.			14-May-26	Gabapentin						
6.			14-May-26	Cefixime						

Premium Content

New Suitability Petition (May - 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.			19-May-26	Mirtazapine						

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