

New Suitability Petitions

2nd July 2025

July 2025



New Suitability Petition (July – 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This report identifies new Suitability Petitions Filed, Accepted/Denied and Approved/Withdrawn.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 (July - 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 | 01-July-25 | Fluoxetine | Prozac 018936 | Capsules | 10,20,40 and 60 mg | Strength | 15 and 30 mg | Link |
| 2. | | Filed | 01-July-25 | Zolpidem Tartrate | Premium Content | | | | | |
| 3. | | Filed | 03-July-25 | Metoprolol Tartrate | | | | | | |
| 4. | | Filed | 07-July-25 | Pimozide | | | | | | |
| 5. | | Filed | 07-July-25 | Tafamidis | | | | | | |
| 6. | | Filed | 18-July-25 | Diclofenac Potassium | | | | | | |
| 7. | | Filed | 21-July-25 | Testosterone Cypionate | | | | | | |

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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 |
| 8. | | Filed | 23-July-25 | Abiraterone Acetate | Premium Content | | | | | |
| 9. | | Filed | 23-July-25 | Sertraline Hydrochloride | | | | | | |
| 10. | | Filed | 24-July-25 | Hydroxyzine Hydrochloride | | | | | | |

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. | | Denied | 31-July-25 | Valacyclovir Hydrochloride | | | | | | |

New Suitability Petition (July - 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 |
| 2. | | Denied | 14-July-25 | Ranolazine | Premium Content | | | | | |
| 3. | | Denied | 09-July-25 | cariprazine hydrochloride | | | | | | |
| 4. | | Denied | 01-July-25 | Meloxicam | | | | | | |
| 5. | | Accepted | 18-July-25 | Gabapentin | | | | | | |
| 6. | | Denied | 24-July-25 | Rimegepant | | | | | | |
| 7. | | Accepted | 15-July-25 | Hydrocortisone | | | | | | |

New Suitability Petition (July - 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. | | Final Approval | 3-Jul - 25 | Buspirone Hydrochloride | Premium Content | | | | | |
| 2. | | Final Approval | 16-Jul - 25 | Nelarabine | | | | | | |

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