# GDUFA Facility Arrears List

Tuesday, October 6, 2026

The following facilities have not satisfied one or more annual facility fee(s) as required under the Generic Drug User Fee Amendments. The facility fee, incurred pursuant to § 744B(a)(4)(A)(i), was due no later than March 04, 2013 for Fiscal Year (FY) 2013, October 18, 2013 for FY 2014, October 1, 2014 for FY 2015, October 1, 2015 for FY 2016, October 3, 2016 for FY 2017, October 2, 2017 for FY 2018, October 1, 2018 for FY 2019, October 1, 2019 for FY 2020, October 1, 2020 for FY 2021, October 1, 2021 for FY 2022, October 3, 2022 for FY 2023, October 2, 2023 for FY 2024, October 1, 2024 for FY2025 AND November 13, 2025 for FY2026. Failure to timely submit the annual facility payment means that the Food and Drug Administration (FDA) will not be able to receive new ANDAs or PASs referencing these facilities within the meaning of § 505(j)(5)(A). The FDA will also not be able to receive applications submitted by the owners, or affiliates of the owners, of these facilities.

All facilities listed with an "N/A" status indicate that the facility paid, withdrawn from all generic drug submissions before an applicable facility fee due date, or did not incur a fee. If your records indicate that a facility fee was previously submitted, please contact CDERCollections@fda.hhs.gov and provide the following information: Facility name, DUNS, FEI number, User Fee Payment I.D. Number (PIN), and the payment method, date and amount. Additionally, if you believe that your facility is not subject to GDUFA fees, please contact CDERCollections@fda.hhs.gov and provide a brief explanation for your reasoning. The Agency will review your explanation and respond to it promptly.

We encourage you to seek verification from your business partners that all applicable fee(s) have been received in full by the Agency in order to minimize the risk that a receipt of an application will be jeopardized.

| FACILITY NAME | FEI Number | Foreign or Domestic | GDUFA OPERATION | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY2017 | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 | FY 2023 | FY 2024 | FY 2025 | FY 2026 |
| ALCHYMARS ICM SM PRIVATE LIMITED | 3005216842 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | API |
| ANDERSONBRECON INC. | 3003015528 | D | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF |
| APEX PHARMACEUTICALS INC | 3006719767 | D | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF | FDF | FDF | FDF | N/A | N/A | N/A |
| APNAR PHARMA LLP | 3011136472 | D | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF |
| ASTREA FONTAINE | 3002807473 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF |
| BIOSINT SPA | 3002806601 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | API | API | API | API | N/A | N/A |
| CAPCIUM INC. | 3017663620 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF | FDF | N/A |
| CHINA CHEMICAL AND PHARMACEUTICAL CORPORATION LTDTAINAN PLANT II | 3008968334 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF | N/A | N/A | N/A | N/A |
| CISEN PHARMACEUTICAL CO.,LTD | 3009982239 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF | FDF | FDF | N/A |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY2017 | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 | FY 2023 | FY 2024 | FY 2025 | FY 2026 |
| ECI PHARMACEUTICALS LLC | 3008798439 | D | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF | FDF | FDF | FDF |
| EI INC | 3005832998 | D | N/A | N/A | N/A | N/A | N/A | N/A | FDF | FDF | FDF | N/A | N/A | N/A | N/A | N/A |
| GLATT GMBH | 3004146501 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF |
| HIBROW HEALTHCARE PRIVATE LIMITED | 3014930305 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF |
| INNOVARE LABS PRIVATE LIMITED | 3015709928 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | API |
| ISOTOPIA MOLECULAR IMAGING | 1000234390 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF |
| JINAN JINDA PHARMACEUTICAL CHEMISTRY CO. LTD. | 3004002973 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | API | N/A | N/A | N/A | N/A | N/A |
| MEDICAP LABORATORIES | 3006370451 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF |
| MURTY PHARMACEUTICALS INC | 1000515343 | D | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF | N/A | N/A | N/A |
| NATIONAL PHARMACEUTICAL INDUSTRIES CO. | 3009659127 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF | N/A |
| PHARMASOL CORPORATION | 1250001 | D | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF | FDF | N/A | N/A |
| PRZEDSIEBIORSTWO PRODUKCYJNO WDROZENIOWE IFOTAM SP ZOO ZAKLA | 3003022124 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | API | API | API | N/A |
| R CHEM (SOMANAHALLI) PVT LTD | 3014002712 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | API | API | API | N/A | N/A | N/A | N/A |

| FACILITY NAME | FEI Number | Foreign or Domestic | GDUFA OPERATION | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY2017 | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 | FY 2023 | FY 2024 | FY 2025 | FY 2026 |
| RIVOPHARM SA | 3005884589 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF |
| SANOFI CHIMIE CENTRE DE PRODUCTION DE ROMAINVILLE | 3002808028 | F | N/A | N/A | N/A | N/A | N/A | N/A | API | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| SARACA LABORATORIES LIMITED | 3004641543 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | API | N/A | N/A | N/A | N/A | N/A |
| Sharon Bio-medicine Limited | 3005925733 | F | FDF | FDF | FDF | FDF | FDF | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| STERLING PHARMACEUTICAL SERVICES, LLC | 3009705561 | D | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF | FDF | FDF | FDF | FDF | FDF |
| Suir Pharma Ireland | 3002806637 | F | N/A | N/A | N/A | N/A | FDF | FDF | FDF | FDF | N/A | N/A | N/A | N/A | N/A | N/A |
| UNIMARK REMEDIES LIMITED | 3004414652 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | API | API | N/A | API | API |
| VISTA PHARMACEUTICALS LIMITED | 3003978209 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF | FDF | FDF | FDF | FDF | FDF | N/A |
| WINDER LABORATORIES, LLC | 3008694072 | D | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF |
| WOCKHARDT LIMITED | 3005289335 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | FDF | N/A | N/A | N/A |
| Yunnan Hande Bio-Tech Co., Ltd | 3002808537 | F | N/A | N/A | N/A | N/A | N/A | API | API | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| ZHONGFU PHARMACEUTICAL CO., LTD. | 3002808105 | F | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | API |