

GDUFA Program Fee Arrears List Wednesday May 6, 2026

The following companies have not satisfied the annual program fee as required under the Generic Drug User Fee Amendments (GDUFA). The program fee, incurred pursuant to FDARA, was due no later than October 1, 2017 for Fiscal Year (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 1, 2022 for FY 2023, October 2, 2023 for FY 2024, October 1, 2024 for FY 2025 and November 13, 2025 for FY 2026. Failure to timely submit the annual program fee means that the Food and Drug Administration (FDA or Agency) will not be able to receive new or pending ANDAs that have not yet been received for filing from these companies, or from affiliates of these companies, within the meaning of FDARA until all outstanding fees are paid.

If your records indicate that the program fee was previously submitted, please contact CDERCollections@fda.hhs.gov and provide the following information: company name, User Fee Payment I.D. Number (PIN), and the payment method, date and amount. Additionally, if you have reasons to believe that your company is not subject to the annual program fee or your company belongs in a different tier, 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 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.

Program Fee Tier In Arrears

| Parent Company | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 | FY 2023 | FY 2024 | FY 2025 | FY 2026 |
|---|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| ABBOTT LABORATORIES | Small | N/A |
| ABC HOLDING CORP | Medium | N/A |
| ACCELRX LABS LLC | Small |
| ALIGNSCIENCE PHARMA INC. | N/A | N/A | N/A | Small | Small | Small | Small | Small | Small |
| AMBIX LABORATORIES | Medium | N/A | N/A | N/A | N/A | N/A | N/A | Small | Small |
| AMERICAN ANTIBIOTICS LLC | Medium | Small | Small | N/A | N/A | N/A | N/A | N/A | N/A |
| ANIMA PHARMACEUTICALS PRIVATE LIMITED | N/A | N/A | PAID | PAID | PAID | PAID | PAID | Small | Small |
| ANTRIM PHARMACEUTICALS LLC | Small | Small | N/A | Small | Small | N/A | N/A | N/A | N/A |
| APEX PHARMACEUTICALS INC | PAID | PAID | Small | N/A | N/A | N/A | N/A | N/A | N/A |
| APNAR PHARMA LP | N/A | PAID | PAID | PAID | Small | Small | Small | Small | Small |
| APOGEE PHARMA, INC. | Small | N/A |
| APOTHEKERNES LABORATORIUM A S | Small | N/A |
| ARCO PHARMACEUTICALS LLC | Small | N/A |
| AREVA PHARMACEUTICALS INC | PAID | Small | Small |
| ASCOT HOSP PHARMACEUTICALS INC | Small | N/A |
| ATHEM HOLDINGS LLC | N/A | N/A | Small | Small | Small | PAID | PAID | Small | Small |
| ATLANTIDE PHARMACEUTICALS AG | N/A | N/A | N/A | PAID | Medium | N/A | N/A | N/A | N/A |
| ATLAS PHARMACEUTICALS LLC | PAID | PAID | Small | Small | N/A | N/A | N/A | N/A | N/A |
| AVACOR PRODUCTS LLC | Small | N/A |
| AVONDALE PHARMACEUTICALS, LLC | N/A | PAID | Small |
| BARADAINA LLC | N/A | N/A | PAID | N/A | N/A | N/A | N/A | Small | PAID |
| BELMORA LLC | Small | Small | N/A |
| BEOFWOLF ASSET MANAGEMENT, LP | N/A | N/A | N/A | N/A | N/A | Small | PAID | N/A | N/A |
| BH CHEMICALS INC | Small | N/A |
| BI-COASTAL PHARMA INTERNATIONAL, LLC | Small | N/A |
| BIO-NUCLEONICS, INC. | Small | Small | Small | N/A | N/A | N/A | N/A | N/A | N/A |
| BIOPHARM DISCOVERY LLC | N/A | N/A | N/A | N/A | Small | N/A | N/A | N/A | N/A |
| CHEMIEWERK HOMBERG | Small | N/A |
| CHROMALLOY LABORATORIES | Small | N/A |
| CISEN PHARMACEUTICAL CO., LTD. | N/A | N/A | N/A | PAID | PAID | Small | Small | Small | Small |
| CM BUNDY CO | Small | N/A |
| CROSSMEDIKA SA | PAID | PAID | PAID | PAID | PAID | Small | Small | Small | Small |
| DISCOVERY THERAPEUTICS LLC | N/A | N/A | N/A | PAID | Small | N/A | N/A | N/A | N/A |
| ECI PHARMACEUTICALS LLC | PAID | PAID | PAID | N/A | N/A | Small | Small | Small | Small |
| ELITE PHARMACEUTICAL TECHNOLOGY (SHANGHAI) CO., LTD | N/A | N/A | N/A | N/A | Small | Small | Small | Small | Small |
| ELYSIUM PHARMACEUTICALS LIMITED | N/A | N/A | Small | Small | Small | Small | Small | Small | N/A |
| EMED MEDICAL COMPANY, LLC | N/A | N/A | N/A | Small | Small | Small | Small | Small | Small |
| EYWA PHARMA PTE LTD | N/A | N/A | PAID | PAID | PAID | Medium | Medium | N/A | N/A |
| EZRA VENTURES LLC | N/A | Small | Small |
| FLAMINGO PHARMACEUTICALS LIMITED | Small | N/A |
| FLEMING AND COMPANY, PHARMACEUTICALS | Small | N/A |
| GENILAC VE SAGLIK URUNLERI SANAYI VE TICARET ANONIM SIRKETI FABRIKASUBESI | N/A | Small |
| GLAXOSMITHKLINE PLC | PAID | N/A | N/A | N/A | N/A | Small | Small | Small | Small |
| HANSAMED INC | Small | Small | Small | N/A | N/A | N/A | N/A | N/A | N/A |
| HIBROW HEALTHCARE PRIVATE LIMITED | N/A | PAID | Medium |
| HYCHECK CORPORATION | Small | N/A |
| INTELLIPHARMACEUTICS CORP | PAID | PAID | Small | Small | Small | Small | Small | Small | N/A |
| INVATECH PHARMA SOLUTIONS LLC | N/A | N/A | N/A | PAID | PAID | Small | Small | Small | Small |
| ISTITUTO BIOCHIMICO ITALIANO GIOVAANNI LORENZINI SPA | PAID | Medium |
| KASCO EFCO LABORATORIES INC DIV BYK GULDEN INC | Small | N/A |
| KEY THERAPEUTICS, LLC | N/A | Small | Small |
| LABORATORIOS APLICACIONES FARMACEUTICAS SA DE CV | Small | N/A |
| LANDELA PHARMACEUTICAL | Small |
| LAVIPHARM LABORATORIES INC | Small | N/A |
| LEDERLE LABORATORIES DIV AMERICAN CYANAMID CO | Medium | N/A |
| LEINER HEALTH PRODUCTS INC | Medium | N/A |
| MARTEC USA LLC | Small | N/A |
| MEDICAP LABORATORIES | N/A | Small |
| MERICON INDUSTRIES INC | Small | N/A |
| MERRO PHARMACEUTICAL CORPORATION LTD | PAID | PAID | PAID | Small | Small | Small | Small | Small | N/A |
| MISEMER PHARMACEUTICAL, INC | N/A | N/A | N/A | PAID | PAID | PAID | Small | PAID | PAID |
| MIZA PHARMACEUTICALS USA INC | Small | N/A |
| MK LABORATORIES INC | Medium | N/A |
| MURTY PHARMACEUTICALS INC | PAID | PAID | PAID | PAID | PAID | Small | N/A | N/A | N/A |
| NAL PHARMACEUTICAL GROUP LIMITED | N/A | N/A | N/A | N/A | N/A | Small | Small | Small | Small |
| NORVIUM BIOSCIENCE LLC | N/A | PAID | Small |

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| Parent Company | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 | FY 2023 | FY 2024 | FY 2025 | FY 2026 |
|--|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| NOSTRUM LABORATORIES, INC. | PAID | PAID | PAID | PAID | PAID | Large | Large | Large | Small |
| NOVELGENIX THERAPEUTICS PRIVATE LIMITED | N/A | N/A | Small | Small | Small | Small | N/A | N/A | N/A |
| ONEX HEALTHCARE HOLDINGS INC | Small | N/A |
| PHARMA LIFE SCIENCES LLC | N/A | N/A | N/A | PAID | Medium | N/A | N/A | N/A | N/A |
| PHARMA SERVE INC SUB TORIGIAN LABORATORIES | Small | N/A |
| PHARMACEUTICAL SOURCING PARTNERS INC | N/A | N/A | PAID | N/A | N/A | Small | N/A | N/A | N/A |
| PHARMACEUTICAL SPECIALIST ASSOC | Small | N/A |
| PHARMACEUTICAL VENTURES LTD | Small | N/A |
| PHARMATON LTD | Small | N/A |
| PICKET PHARMACEUTICALS, INC. | N/A | N/A | N/A | N/A | Small | Small | N/A | N/A | N/A |
| POLYGEN PHARMACEUTICALS INC | N/A | N/A | N/A | PAID | PAID | Small | Small | Small | Small |
| PREMO PHARMACEUTICAL LABORATORIES INC | Small | N/A |
| PROPEL PHARMA CORP | N/A | N/A | N/A | N/A | N/A | PAID | PAID | Small | N/A |
| Q BIOMED INC. | N/A | N/A | N/A | PAID | PAID | Small | Small | Small | Small |
| REXALL DRUG CO | Small | N/A |
| SAI LIFE SCIENCES LTD | N/A | N/A | Small | N/A | N/A | N/A | N/A | N/A | N/A |
| SANKALP LIFECARE INC | N/A | Small |
| SANOCHEMIA CORP USA | PAID | PAID | Small | N/A | N/A | N/A | N/A | N/A | N/A |
| SHREE HARI INTERNATIONAL LLC | N/A | N/A | N/A | N/A | N/A | N/A | Small | Small | Small |
| SOAPCO INC | Small | N/A |
| SOCORRO NST-1, LLC | N/A | N/A | Small | Small | N/A | N/A | N/A | N/A | N/A |
| STAR PHARMACEUTICALS INC | Small | Small | N/A |
| SYOSSET LABORATORIES INC | Small | N/A |
| TELIGENT PHARMA, INC. | PAID | PAID | PAID | PAID | PAID | N/A | N/A | N/A | Small |
| TG UNITED INC. | Small | Small | Small | Small | Small | Small | N/A | N/A | Small |
| TRACE LIFE SCIENCES INC | Small | N/A |
| ULTRATAB LABORATORIES INC | N/A | N/A | N/A | Small | N/A | N/A | N/A | N/A | N/A |
| UNICORN PHARMACEUTICALS | N/A | N/A | N/A | Small | Small | N/A | N/A | N/A | N/A |
| UNIMARK REMEDIES LIMITED | PAID | PAID | PAID | PAID | Small | Small | Small | Small | N/A |
| VILIN BIO MED LIMITED | N/A | Small |
| VISTA PHARMACEUTICALS INC | PAID | PAID | Small |
| WES PHARMA INC | PAID | Medium | PAID |
| WINDER LABORATORIES, LLC | N/A | N/A | N/A | N/A | PAID | PAID | PAID | PAID | Small |
| WOCKHARDT BIO AG | PAID | PAID | PAID | PAID | PAID | PAID | Large | Large | Large |
| XANODYNE PHARMACEUTICALS INC | Small | N/A |
| XSPIRE PHARMA LLC | Small | PAID | PAID | PAID | PAID | Small | Small | N/A | N/A |
| ZZEON PHARMACEUTICALS LTD | Small | N/A |