GDUFA Program Fee Arrears List
Friday October 30, 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, November 13, 2025 for FY 2026, and October 1, 2026 for FY 2027. 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 FDAUserFees@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 FDAUserFees@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**	**FY 2027**
ABBOTT LABORATORIES	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ABC HOLDING CORP	Medium	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ACCELRX LABS LLC	Small	Small	Small	Small	Small	Small	Small	Small	Small	Small
ALIGNSCIENCE PHARMA INC.	N/A	N/A	N/A	Small	Small	Small	Small	Small	Small	Small
AMBIX LABORATORIES	Medium	N/A	N/A	N/A	N/A	N/A	N/A	Small	Small	N/A
AMERICAN ANTIBIOTICS LLC	Medium	Small	Small	N/A	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	N/A
ANTRIM PHARMACEUTICALS LLC	Small	Small	N/A	Small	Small	N/A	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	N/A
APNAR PHARMA LP	N/A	PAID	PAID	PAID	Small	Small	Small	Small	Small	N/A
APOGEE PHARMA, INC.	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
APOTHEKERNES LABORATORIUM A S	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ARCO PHARMACEUTICALS LLC	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
AREVA PHARMACEUTICALS	PAID	PAID	PAID	PAID	PAID	PAID	PAID	Small	Small	Small
ASCOT HOSP PHARMACEUTICALS INC	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ATHEM HOLDINGS LLC	N/A	N/A	Small	Small	Small	PAID	PAID	Small	Small	N/A
ATLANTIDE PHARMACEUTICALS AG	N/A	N/A	N/A	PAID	Medium	N/A	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	N/A
AVACOR PRODUCTS LLC	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
AVERION LIFE SCIENCES, INC	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Small
AVONDALE PHARMACEUTICALS, LLC	N/A	PAID	PAID	PAID	PAID	PAID	PAID	PAID	PAID	Small
AYANA PHARMA LTD	N/A	N/A	N/A	N/A	N/A	PAID	PAID	PAID	PAID	Small
BAJAJ MEDICAL, LLC	N/A	PAID	PAID	PAID	PAID	PAID	PAID	PAID	PAID	Small
BARADAINA LLC	N/A	N/A	PAID	N/A	N/A	N/A	N/A	Small	PAID	N/A
BELMORA LLC	Small	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
BEOWULF ASSET MANAGEMENT, LP	N/A	N/A	N/A	N/A	N/A	Small	PAID	N/A	N/A	N/A
BH CHEMICALS INC	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
BI-COASTAL PHARMA INTERNATIONAL, LLC	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
BIO-NUCLEONICS, INC.	Small	Small	Small	N/A	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	N/A
CHEMIEWERK HOMBERG	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CHROMALLOY LABORATORIES	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CISEN PHARMACEUTICAL CO., LTD.	N/A	N/A	N/A	PAID	PAID	Small	Small	Small	Small	N/A
CM BUNDY CO	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CROSSMEDIKA S.A.	PAID	PAID	PAID	PAID	PAID	Small	Small	Small	Small	Small
CSL PLASMA, INC.	N/A	N/A	N/A	N/A	N/A	PAID	PAID	PAID	PAID	Small
DENTSPLY PHARMACEUTICAL	PAID	PAID	PAID	PAID	PAID	PAID	PAID	PAID	PAID	Small
DISCOVERY THERAPEUTICS LLC	N/A	N/A	N/A	PAID	Small	N/A	N/A	N/A	N/A	N/A
E5 PHARMA, LLC	N/A	N/A	N/A	PAID	PAID	PAID	PAID	PAID	PAID	Small
ECI PHARMACEUTICALS LLC	PAID	PAID	PAID	N/A	N/A	Small	Small	Small	Small	Small
ELITE PHARMACEUTICAL TECHNOLOGY (SHANGHAI) CO., LTD	N/A	N/A	N/A	N/A	Small	Small	Small	Small	Small	Small
ELYSIUM PHARMACEUTICALS LTD	N/A	N/A	Small	Small	Small	Small	Small	Small	N/A	Small
EMED MEDICAL COMPANY, LLC	N/A	N/A	N/A	Small	Small	Small	Small	Small	Small	Small
EVEREST LIFE SCIENCES LLC	N/A	N/A	N/A	N/A	N/A	N/A	PAID	PAID	PAID	Small
EXELA PHARMA SCIENCES, LLC	PAID	PAID	PAID	PAID	PAID	PAID	PAID	PAID	PAID	Medium
EYWA PHARMA PTE LTD	N/A	N/A	PAID	PAID	PAID	Medium	Medium	N/A	N/A	N/A
EZRA VENTURES LLC	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Small	Small	Small
FLAMINGO PHARMACEUTICALS LIMITED	Small	Small	Small	Small	Small	Small	Small	Small	N/A	N/A
FLEMING AND COMPANY, PHARMACEUTICALS	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
GALENICUM HEALTH, S.L.U.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	PAID	Small
GALT PHARMACEUTICALS, LLC	N/A	PAID	PAID	PAID	PAID	PAID	PAID	PAID	PAID	Small
GENUS LIFESCIENCES INC	N/A	N/A	PAID	PAID	PAID	PAID	PAID	PAID	PAID	Medium
GLAXOSMITHKLINE PLC	PAID	N/A	N/A	N/A	N/A	Small	Small	Small	Small	Small
HANSAMED INC	Small	Small	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A
HIBROW HEALTHCARE PRIVATE LIMITED	N/A	N/A	N/A	N/A	N/A	N/A	N/A	PAID	Medium	N/A
HYCHECK CORPORATION	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
INDIES PHARMA JAMAICA LIMITED	N/A	N/A	N/A	N/A	N/A	N/A	N/A	PAID	PAID	Small
INTELLIPHARMACEUTICS CORP	PAID	PAID	Small	Small	Small	Small	Small	Small	N/A	N/A
INVATECH PHARMA SOLUTIONS LLC	N/A	N/A	N/A	PAID	PAID	Small	Small	Small	Small	Small
KASCO EFCO LABORATORIES INC	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
KEY THERAPEUTICS, LLC	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Small	Small	Small
LABORATORIOS APLICACIONES FARMACEUTICAS SA DE CV	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
LANDELA PHARMACEUTICAL	Small	Small	Small	Small	Small	Small	Small	Small	Small	Small
LANTHEUS MEDICAL IMAGING, INC.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Small
LAVIPHARM LABORATORIES INC	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
LEDERLE LABORATORIES DIV AMERICAN CYANAMID CO	Medium	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
LEINER HEALTH PRODUCTS INC	Medium	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MARTEC USA LLC	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MEDICAP LABORATORIES	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Small	N/A

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Parent Company	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
MERICON INDUSTRIES INC	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MERRO PHARMACEUTICAL CORPORATION LTD	PAID	PAID	PAID	Small	Small	Small	Small	Small	N/A	N/A
MISEMER PHARMACEUTICALS, INC.	N/A	N/A	N/A	PAID	PAID	PAID	Small	PAID	PAID	Small
MISSION PHARMACAL COMPANY	PAID	PAID	PAID	PAID	PAID	PAID	PAID	PAID	PAID	Small
MIZA PHARMACEUTICALS USA INC	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MK LABORATORIES INC	Medium	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MPP PHARMA LLC	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	PAID	Medium
MURTY PHARMACEUTICALS, INC.	PAID	PAID	PAID	PAID	PAID	Small	N/A	N/A	N/A	N/A
NAL PHARMACEUTICAL GROUP LIMITED	N/A	N/A	N/A	N/A	PAID	Small	Small	Small	Small	Small
NOSTRUM LABORATORIES, INC.	PAID	PAID	PAID	PAID	PAID	Large	Large	Large	Small	N/A
NOVELGENIX THERAPEUTICS PRIVATE LIMITED	N/A	N/A	Small	Small	Small	Small	N/A	N/A	N/A	N/A
NUVO PHARMACEUTICALS, INC.	PAID	PAID	PAID	PAID	PAID	PAID	PAID	PAID	PAID	Medium
ONEX HEALTHCARE HOLDINGS INC	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PHARMA LIFE SCIENCES LLC	N/A	N/A	N/A	PAID	Medium	N/A	N/A	N/A	N/A	N/A
PHARMA SERVE INC	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PHARMACEUTICAL SOURCING PARTNERS INC	N/A	N/A	PAID	N/A	N/A	Small	N/A	N/A	N/A	N/A
PHARMACEUTICAL SPECIALIST ASSOC	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PHARMACEUTICAL VENTURES LTD	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PHARMATON LTD	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PICKET PHARMACEUTICALS, INC.	N/A	N/A	N/A	N/A	Small	Small	N/A	N/A	N/A	N/A
PLATINUM PHARMACEUTICALS	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Small
POLYGEN PHARMACEUTICALS INC.	N/A	N/A	N/A	PAID	PAID	Small	Small	Small	Small	N/A
PREMO PHARMACEUTICAL LABORATORIES INC	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
PROPEL PHARMA CORP	N/A	N/A	N/A	N/A	N/A	PAID	PAID	Small	N/A	N/A
PURE SOURCE, LLC	N/A	N/A	N/A	N/A	N/A	PAID	PAID	PAID	PAID	Small
Q BIOMED INC.	N/A	N/A	N/A	PAID	PAID	Small	Small	Small	Small	Small
REXALL DRUG CO	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
SAI LIFE SCIENCES LTD	N/A	N/A	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A
SANKALP LIFECARE INC	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Small	Small
SANOCHEMIA CORP USA	PAID	PAID	Small	N/A	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	Small
SOAPCO INC	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
SOCORRO NST-1, LLC	N/A	N/A	Small	Small	N/A	N/A	N/A	N/A	N/A	N/A
SOLUBIOMIX LLC	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	PAID	Small
STAR PHARMACEUTICALS INC	Small	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
STIRA PHARMACEUTICALS LLC	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Small
SYOSSET LABORATORIES INC	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
TELIGENT PHARMA, INC.	PAID	PAID	PAID	PAID	PAID	N/A	N/A	N/A	Small	Small
TERUMO BCT, INC.	PAID	PAID	PAID	PAID	PAID	PAID	PAID	PAID	PAID	Small
TG UNITED, INC.	Small	Small	Small	Small	Small	Small	N/A	N/A	N/A	N/A
TRACE LIFE SCIENCES INC	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ULTRATAB LABORATORIES INC.	N/A	N/A	N/A	Small	N/A	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	N/A
UNIMARK REMEDIES LIMITED	PAID	PAID	PAID	PAID	Small	Small	Small	Small	N/A	N/A
VILIN BIO MED LIMITED	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Small	Small
VISTA PHARMACEUTICALS, INC.	PAID	PAID	Small	Small	Small	Small	Small	Small	Small	Small
WES PHARMA INC.	PAID	PAID	PAID	PAID	PAID	PAID	PAID	Medium	PAID	PAID
WINDER LABORATORIES, LLC	N/A	N/A	N/A	N/A	PAID	PAID	PAID	PAID	Small	Small
WOCKHARDT BIO AG	PAID	PAID	PAID	PAID	PAID	PAID	Large	Large	Large	Large
XANODYNE PHARMACEUTICALS INC	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
XSPIRE PHARMA, LLC	Small	PAID	PAID	PAID	PAID	Small	Small	N/A	N/A	N/A
ZENNOVA PHARMACEUTICALS (CHENGDU) CO.,LTD.	N/A	N/A	PAID	PAID	PAID	PAID	PAID	PAID	N/A	Small
ZHEJIANG BAYSIDE BIOTECH CO., LTD.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	PAID	Small
ZZEON PHARMACEUTICALS LTD	Small	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A