

The following companies have not satisfied the annual program fee as required under the Generic Drug User Fee Amendments of 2017 (GDUFA II) under Title III of the FDA Reauthorization Act of 2017 (FDARA). 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, and October 1, 2021 for FY 2022. 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 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.

Parent Company Name	Program Fee Tier In Arrears				
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
ABBOTT LABORATORIES PHARMACEUTICAL PRODUCTS DIV	Small	N/A	N/A	N/A	N/A
ABC HOLDING CORP	Medium	N/A	N/A	N/A	N/A
ACCELRX LABS LLC	Small	Small	Small	Small	Small
ACELLA PHARMACEUTICALS, LLC	PAID	PAID	PAID	PAID	Medium
ALIGNSCIENCE PHARMA INC.	N/A	N/A	N/A	Small	Small
ALRA LABORATORIES INC	Large	N/A	N/A	N/A	N/A
AMBIX LABORATORIES	Medium	N/A	N/A	N/A	N/A
AMERICAN ANTIBIOTICS LLC	Medium	Small	Small	N/A	N/A
ANTRIM PHARMACEUTICALS LLC	Small	Small	N/A	Small	Small
APEX PHARMACEUTICALS INC	PAID	PAID	Small	N/A	N/A
APNAR PHARMA LP	N/A	PAID	PAID	PAID	Small
APOGEE PHARMA, INC.	Small	N/A	N/A	N/A	N/A
APOTHEKERNES LABORATORIUM A S	Small	N/A	N/A	N/A	N/A
ARCO PHARMACEUTICALS LLC	Small	N/A	N/A	N/A	N/A
AREVA PHARMACEUTICALS INC	PAID	PAID	PAID	PAID	Small
ARISE PHARMACEUTICALS LLC	N/A	PAID	PAID	PAID	Small
ASCOT HOSP PHARMACEUTICALS INC	Small	N/A	N/A	N/A	N/A

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	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
ATHEM HOLDINGS LLC	N/A	N/A	Small	Small	Small
ATLANTIDE PHARMACEUTICALS AG	N/A	N/A	N/A	PAID	Medium
ATLAS PHARMACEUTICALS LLC	PAID	PAID	Small	Small	Small
AVACOR PRODUCTS LLC	Small	N/A	N/A	N/A	N/A
BEDFORD LABORATORIES	Small	N/A	N/A	N/A	N/A
BELMORA LLC	Small	Small	N/A	N/A	N/A
BH CHEMICALS INC	Small	N/A	N/A	N/A	N/A
BI-COASTAL PHARMA INTERNATIONAL, LLC	Small	N/A	N/A	N/A	N/A
BIOGLAN LABORATORIES LTD	Small	N/A	N/A	N/A	N/A
BIO-NUCLEONICS, INC.	Small	Small	Small	N/A	N/A
BIOPHARM DISCOVERY LLC	N/A	N/A	N/A	N/A	Small
C AND M PHARMACAL INC	Small	N/A	N/A	N/A	N/A
CAMALL CO INC	Small	N/A	N/A	N/A	N/A
CEPH INTERNATIONAL CORP	Small	N/A	N/A	N/A	N/A
CHEMIEWERK HOMBERG	Small	N/A	N/A	N/A	N/A
CHROMALLOY LABORATORIES	Small	N/A	N/A	N/A	N/A
CM BUNDY CO	Small	N/A	N/A	N/A	N/A
DELL LABORATORIES INC	Small	N/A	N/A	N/A	N/A
DENTSPLY PHARMACEUTICAL	PAID	PAID	PAID	PAID	Small
DISCOVERY THERAPEUTICS LLC	N/A	N/A	N/A	PAID	Small
EI LLC	PAID	Small	Small	Small	Small
ELITE PHARMACEUTICAL TECHNOLOGY (SHANGHAI) CO., LTD	N/A	N/A	N/A	N/A	Small
ELYSIUM PHARMACEUTICALS LIMITED	N/A	N/A	Small	Small	Small

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EMED MEDICAL COMPANY, LLC	N/A	N/A	N/A	Small	Small
EMERALD INTERNATIONAL LTD	PAID	PAID	PAID	PAID	Small
EVERYLIFE	Small	N/A	N/A	N/A	N/A
FERA PHARMACEUTICALS LLC	PAID	PAID	PAID	PAID	Small
FLAMINGO PHARMACEUTICALS LIMITED	Small	Small	Small	Small	Small
FLEMING AND COMPANY, PHARMACEUTICALS	Small	N/A	N/A	N/A	N/A
GALT PHARMACEUTICALS LLC	N/A	PAID	PAID	Small	Small
GLENWOOD INC	Small	N/A	N/A	N/A	N/A
GLW PHARMA GMBH	N/A	N/A	N/A	PAID	Small
GRANATA BIO CORPORATION	N/A	N/A	N/A	Small	Small
HANSAMED INC	Small	Small	Small	N/A	N/A
HOLLAND RANTOS CO INC	Small	N/A	N/A	N/A	N/A
HYBIO PHARMACEUTICAL CO LTD	N/A	N/A	N/A	PAID	Small
HYCHECK CORPORATION	Small	N/A	N/A	N/A	N/A
IDENTI PHARMACEUTICALS	PAID	PAID	PAID	N/A	Small
INTELLIPHARMACEUTICS CORP	PAID	PAID	Small	Small	Small
INVATECH PHARMA SOLUTIONS LLC	N/A	N/A	N/A	Small	Small
JOHN D COPANOS AND CO INC	Small	N/A	N/A	N/A	N/A
KASCO EFCO LABORATORIES INC DIV BYK GULDEN INC	Small	N/A	N/A	N/A	N/A
LABORATORIOS APLICACIONES FARMACEUTICAS SA DE CV	Small	N/A	N/A	N/A	N/A
LANDELA PHARMACEUTICAL	Small	Small	Small	Small	Small
LAVIPHARM LABORATORIES INC	Small	N/A	N/A	N/A	N/A
LEDERLE LABORATORIES DIV AMERICAN CYANAMID CO	Medium	N/A	N/A	N/A	N/A
LEINER HEALTH PRODUCTS INC	Medium	N/A	N/A	N/A	N/A

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MARSHALL PHARMACAL CORP	Small	N/A	N/A	N/A	N/A
MARTEC USA LLC	Small	N/A	N/A	N/A	N/A
MATRIX MEDICAL CORP	Small	N/A	N/A	N/A	N/A
MERICON INDUSTRIES INC	Small	N/A	N/A	N/A	N/A
MERRO PHARMACEUTICAL CORPORATION LTD	PAID	PAID	PAID	Small	Small
MIZA PHARMACEUTICALS USA INC	Small	N/A	N/A	N/A	N/A
MK LABORATORIES INC	Medium	N/A	N/A	N/A	N/A
MM MAST AND CO	Small	N/A	N/A	N/A	N/A
MONTEREY PHARMACEUTICALS LLC	Small	Small	Small	Small	Small
NAL PHARMACEUTICAL GROUP LIMITED	N/A	N/A	N/A	N/A	Small
NORTEC DEVELOPMENT ASSOC INC	PAID	Small	PAID	PAID	PAID
NORTHSTAR HEALTHCARE HOLDINGS	PAID	PAID	PAID	PAID	Small
NOVELGENIX THERAPEUTICS PRIVATE LIMITED	N/A	N/A	Small	Small	Small
ONEX HEALTHCARE HOLDINGS INC	Small	N/A	N/A	N/A	N/A
OPTOPICS LABORATORIES CORP	Small	N/A	N/A	N/A	N/A
PHARMA LIFE SCIENCES LLC	N/A	N/A	N/A	PAID	Medium
PHARMA SERVE INC SUB TORIGIAN LABORATORIES	Small	N/A	N/A	N/A	N/A
PHARMACEUTICAL SPECIALIST ASSOC	Small	N/A	N/A	N/A	N/A
PHARMACEUTICAL VENTURES LTD	Small	N/A	N/A	N/A	N/A
PHARMATON LTD	Small	N/A	N/A	N/A	N/A
PHARMERAL INC	Small	Small	Small	Small	Small
PHOENIX LABORATORIES INC	Small	N/A	N/A	N/A	N/A
PICKET PHARMACEUTICALS, INC.	N/A	N/A	N/A	N/A	Small
POLYMEDICA INDUSTRIES INC	Small	N/A	N/A	N/A	N/A

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PREMO PHARMACEUTICAL LABORATORIES INC	Small	N/A	N/A	N/A	N/A
PRIVATE FORMULATIONS INC	Small	N/A	N/A	N/A	N/A
PROTER LABORATORY SPA	Small	N/A	N/A	N/A	N/A
REXALL DRUG CO	Small	N/A	N/A	N/A	N/A
ROUSES POINT PHARMACEUTICALS LLC	N/A	PAID	PAID	Small	Small
SAI LIFE SCIENCES LTD	N/A	N/A	Small	N/A	N/A
SANOCHEMIA CORP USA	PAID	PAID	Small	N/A	N/A
SCHERER LABORATORIES INC	Small	N/A	N/A	N/A	N/A
SHIRE RICHWOOD INC	Medium	N/A	N/A	N/A	N/A
SOAPCO INC	Small	N/A	N/A	N/A	N/A
SOCORRO NST-1, LLC	N/A	N/A	Small	Small	N/A
SOMMER PHARMACEUTICALS II LLC	N/A	N/A	N/A	Small	Small
STAR PHARMACEUTICALS INC	Small	Small	N/A	N/A	N/A
SYOSSET LABORATORIES INC	Small	N/A	N/A	N/A	N/A
TABLICAPS INC	Small	N/A	N/A	N/A	N/A
TERSERA THERAPEUTICS LLC	N/A	N/A	PAID	PAID	Small
TG UNITED INC.	Small	Small	Small	Small	Small
THERAGEN INC	Small	N/A	N/A	N/A	N/A
TRACE LIFE SCIENCES INC	Small	N/A	N/A	N/A	N/A
ULTRATAB LABORATORIES INC	N/A	N/A	N/A	Small	N/A
UNICORN PHARMACEUTICALS	N/A	N/A	N/A	Small	Small
UNIMARK REMEDIES LIMITED	PAID	PAID	PAID	PAID	Small
VIRTUS PHARMACEUTICALS, LLC	PAID	PAID	PAID	PAID	Medium
VISTA PHARMACEUTICALS INC	PAID	PAID	Small	Small	Small

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WE PHARMACEUTICALS INC	Small	N/A	N/A	N/A	N/A
WENDT LABORATORIES INC	Medium	N/A	N/A	N/A	N/A
WINDER LABORATORIES LLC	N/A	N/A	N/A	N/A	Small
WRASER PHARMACEUTICALS LLC	PAID	PAID	PAID	PAID	Small
XANODYNE PHARMACEUTICALS INC	Small	N/A	N/A	N/A	N/A
XSPIRE PHARMA LLC	Small	PAID	PAID	PAID	PAID
YANGLING BUCHANG PHARMACEUTICAL CO LTD	N/A	N/A	N/A	N/A	Small
ZO SKIN HEALTH	PAID	PAID	PAID	PAID	Small
ZZEON PHARMACEUTICALS LTD	Small	N/A	N/A	N/A	N/A