

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
ABBOTT LABORATORIES	Small	N/A	N/A	N/A
ABC HOLDING CORP	Medium	N/A	N/A	N/A
ACCELRX LABS LLC	Small	Small	Small	Small
ALAN LABORATORIES, INC.	N/A	N/A	N/A	Small
ALIGNSCIENCE PHARMA INC.	N/A	N/A	N/A	Small
ALRA LABORATORIES INC	Large	N/A	N/A	N/A
AMBIX LABORATORIES	Medium	N/A	N/A	N/A
AMERICAN ANTIBIOTICS LLC	Medium	Small	Small	N/A
ANTRIM PHARMACEUTICALS LLC	Small	Small	N/A	Small
APEX PHARMACEUTICALS INC	PAID	PAID	Small	N/A
APOGEE PHARMA INC	Small	N/A	N/A	N/A
APOTHEKERNES LABORATORIUM A S	Small	N/A	N/A	N/A
ARCO PHARMACEUTICALS LLC	Small	N/A	N/A	N/A
ASCOT HOSP PHARMACEUTICALS INC	Small	N/A	N/A	N/A
ATHEM HOLDINGS LLC	N/A	N/A	Small	Small
ATLAS PHARMACEUTICALS LLC	PAID	PAID	Small	Small
AVACOR PRODUCTS LLC	Small	N/A	N/A	N/A

Parent Company Name	Program Fee Tier In Arrears			
	FY 2018	FY 2019	FY 2020	FY 2021
BEDFORD LABORATORIES	Small	N/A	N/A	N/A
BELMORA LLC	Small	Small	N/A	N/A
BH CHEMICALS INC	Small	N/A	N/A	N/A
BI-COASTAL PHARMA INTERNATIONAL, LLC	Small	N/A	N/A	N/A
BIOGLAN LABORATORIES LTD	Small	N/A	N/A	N/A
BIO-NUCLEONICS, INC.	Small	Small	Small	N/A
C AND M PHARMACAL INC	Small	N/A	N/A	N/A
CAMALL CO INC	Small	N/A	N/A	N/A
CEPH INTERNATIONAL CORP	Small	N/A	N/A	N/A
CHEMIEWERK HOMBERG	Small	N/A	N/A	N/A
CHROMALLOY LABORATORIES DIV CHROMALLOY PHARMACEUTICALS INC	Small	N/A	N/A	N/A
CM BUNDY CO	Small	N/A	N/A	N/A
DELL LABORATORIES INC	Small	N/A	N/A	N/A
DENTSPLY PHARMACEUTICAL	PAID	PAID	PAID	Small
DFB ONCOLOGY LTD	PAID	PAID	PAID	Small
EI LLC	PAID	Small	Small	Small
ELYSIUM PHARMACEUTICALS LIMITED	N/A	N/A	Small	Small
EVERYLIFE	Small	N/A	N/A	N/A
FLAMINGO PHARMACEUTICALS LIMITED	Small	Small	Small	Small
FLEMING AND COMPANY, PHARMACEUTICALS	Small	N/A	N/A	N/A
GALDERMA LABORATORIES LP	PAID	PAID	PAID	Small
GALT PHARMACEUTICALS LLC	N/A	PAID	PAID	Small
GENZUM LIFE SCIENCES LLC	N/A	N/A	N/A	Small
GLENWOOD INC	Small	N/A	N/A	N/A

Parent Company Name	Program Fee Tier In Arrears			
	FY 2018	FY 2019	FY 2020	FY 2021
GRANATA BIO CORPORATION	N/A	N/A	N/A	Small
HANSAMED INC	Small	Small	Small	N/A
HARRIS PHARMACEUTICAL INC	PAID	PAID	PAID	Small
HIKAL LIMITED	N/A	N/A	N/A	Small
HOLLAND RANTOS CO INC	Small	N/A	N/A	N/A
HYPHECK CORPORATION	Small	N/A	N/A	N/A
INTELLIPHARMACEUTICS CORP	PAID	PAID	Small	Small
INVATECH PHARMA SOLUTIONS LLC	N/A	N/A	N/A	Small
JOHN D COPANOS AND CO INC	Small	N/A	N/A	N/A
KASCO EFCO LABORATORIES INC DIV BYK GULDEN INC	Small	N/A	N/A	N/A
LABORATORIOS APLICACIONES FARMACEUTICAS SA DE CV	Small	N/A	N/A	N/A
LANDELA PHARMACEUTICAL	Small	Small	Small	Small
LAVIPHARM LABORATORIES INC	Small	N/A	N/A	N/A
LEDERLE LABORATORIES DIV AMERICAN CYANAMID CO	Medium	N/A	N/A	N/A
LEINER HEALTH PRODUCTS INC	Medium	N/A	N/A	N/A
MARSHALL PHARMACAL CORP	Small	N/A	N/A	N/A
MARTEC USA LLC	Small	N/A	N/A	N/A
MATRIX MEDICAL CORP	Small	N/A	N/A	N/A
MERICON INDUSTRIES INC	Small	N/A	N/A	N/A
MERRO PHARMACEUTICAL CORPORATION LTD	PAID	PAID	PAID	Small
MISEMER PHARMACEUTICAL	N/A	N/A	N/A	Small
MIZA PHARMACEUTICALS USA INC	Small	N/A	N/A	N/A
MK LABORATORIES INC	Medium	N/A	N/A	N/A
MM MAST AND CO	Small	N/A	N/A	N/A

Parent Company Name	Program Fee Tier In Arrears			
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MONTEREY PHARMACEUTICALS LLC	Small	Small	Small	Small
NEOPHARMA INCORPORATED	N/A	PAID	PAID	Medium
NEOS THERAPEUTICS, LP	PAID	PAID	PAID	Small
NORTEC DEVELOPMENT ASSOCS INC GLATT AIR TECHNIQUES INC	PAID	Small	PAID	Small
NOVELGENIX THERAPEUTICS PRIVATE LIMITED	N/A	N/A	Small	Small
ONEX HEALTHCARE HOLDINGS INC	Small	N/A	N/A	N/A
OPTOPICS LABORATORIES CORP	Small	N/A	N/A	N/A
PHARMA SERVE INC SUB TORIGIAN LABORATORIES	Small	N/A	N/A	N/A
PHARMACEUTICAL SPECIALIST ASSOC	Small	N/A	N/A	N/A
PHARMACEUTICAL VENTURES LTD	Small	N/A	N/A	N/A
PHARMATON LTD	Small	N/A	N/A	N/A
PHARMERAL INC	Small	Small	Small	Small
PHOENIX LABORATORIES INC	Small	N/A	N/A	N/A
POLYMEDICA INDUSTRIES INC	Small	N/A	N/A	N/A
PREMO PHARMACEUTICAL LABORATORIES INC	Small	N/A	N/A	N/A
PRIVATE FORMULATIONS INC	Small	N/A	N/A	N/A
PROTER LABORATORY SPA	Small	N/A	N/A	N/A
REXALL DRUG CO	Small	N/A	N/A	N/A
RHODES PHARMACEUTICALS LP	PAID	PAID	PAID	Large
ROUSES POINT PHARMACEUTICALS LLC	N/A	Small	Small	Small
SAI LIFE SCIENCES LTD	N/A	N/A	Small	N/A
SANOCHEMIA CORP USA	PAID	PAID	Small	N/A
SCHERER LABORATORIES INC	Small	N/A	N/A	N/A
SHIRE RICHWOOD INC	Medium	N/A	N/A	N/A

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SOAPCO INC	Small	N/A	N/A	N/A
SOCORRO NST-1, LLC	N/A	N/A	Small	Small
SOMMER PHARMACEUTICALS II LLC	N/A	N/A	N/A	Small
STAR PHARMACEUTICALS INC	Small	Small	N/A	N/A
SYOSSET LABORATORIES INC	Small	N/A	N/A	N/A
TABLICAPS INC	Small	N/A	N/A	N/A
TG UNITED	Small	Small	Small	Small
THERAGEN INC	Small	N/A	N/A	N/A
TRACE LIFE SCIENCES INC	Small	N/A	N/A	N/A
ULTRATAB LABORATORIES INC	N/A	N/A	N/A	Small
UNICORN PHARMACEUTICALS	N/A	N/A	N/A	Small
UNIMARK REMEDIES LIMITED	PAID	PAID	PAID	Small
VISTA PHARMACEUTICALS INC	PAID	PAID	Small	Small
WE PHARMACEUTICALS INC	Small	N/A	N/A	N/A
WENDT LABORATORIES INC	Medium	N/A	N/A	N/A
XANODYNE PHARMACEUTICALS INC	Small	N/A	N/A	N/A
XSPIRE PHARMA LLC	Small	PAID	PAID	PAID
ZENNOVA LLC	N/A	N/A	Small	Small
ZZEON PHARMACEUTICALS LTD	Small	N/A	N/A	N/A