

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
ABBOTT LABORATORIES PHARMACEUTICAL PRODUCTS DIV	Small	N/A
ABC HOLDING CORP	Medium	N/A
ACCELRX LABS LLC	Small	Small
ALLIED PHARMA INC	Paid	Small
ALRA LABORATORIES INC	Large	N/A
AMBIX LABORATORIES DIV ORGANICS CORP AMERICA	Medium	N/A
AMERICAN ANTIBIOTICS INC	Medium	Small
ANTRIM PHARMACEUTICALS LLC	Small	Small
APC PHARMACEUTICALS LLC	N/A	Small
APNAR PHARMA LP	N/A	Small
APOGEE PHARMA INC	Small	N/A
APOTHEKERNES LABORATORIUM A S	Small	N/A
ARCO PHARMACEUTICALS LLC	Small	N/A
ARTERIOCYTE MEDICAL SYSTEMS, INC.	Small	Small
ASCOT HOSP PHARMACEUTICALS INC DIV TRAVENOL LABORATORIES INC	Small	Small
AVACOR PRODUCTS LLC	Small	N/A
BEDFORD LABORATORIES DIV BEN VENUE LABORATORIES INC	Small	N/A

Parent Company Name	Program Fee Tier In Arrears	
	FY 2018	FY 2019
BELMORA LLC	Small	Small
BH CHEMICALS INC	Small	N/A
BI-COASTAL PHARMA INTERNATIONAL LLC	Small	N/A
BIO NUCLEONICS INC	Small	Small
BIOGLAN LABORATORIES LTD	Small	N/A
C AND M PHARMACAL INC	Small	N/A
CAMALL CO INC	Small	N/A
CEPH INTERNATIONAL CORP	Small	N/A
CHEMIEWERK HOMBERG	Small	N/A
CHROMALLOY LABORATORIES DIV CHROMALLOY PHARMACEUTICALS INC	Small	N/A
CM BUNDY CO	Small	N/A
DELL LABORATORIES INC	Small	N/A
EI INC	Paid	Small
EVERYLIFE Corp	Small	N/A
FLAMINGO PHARMACEUTICALS LTD	Small	Small
FLEMING AND CO PHARMACEUTICALS INC	Small	N/A
FUTURE PAK LTD	Small	N/A
GLENWOOD INC	Small	N/A
HANSAMED INC	Small	Small
HOLLAND RANTOS CO INC	Small	N/A
HYCHECK CORPORATION	Small	N/A
JOHN D COPANOS AND CO INC	Small	N/A
KASCO EFCO LABORATORIES INC DIV BYK GULDEN INC	Small	N/A
LABORATORIOS APLICACIONES FARMACEUTICAS SA DE CV	Small	N/A

Parent Company Name	Program Fee Tier In Arrears	
	FY 2018	FY 2019
LANDELA PHARMACEUTICAL	Small	Small
LAVIPHARM LABORATORIES INC	Small	N/A
LEDERLE LABORATORIES DIV AMERICAN CYANAMID CO	Medium	N/A
LEINER HEALTH PRODUCTS INC	Medium	N/A
MARSHALL PHARMACAL CORP	Small	N/A
MARTEC USA LLC	Small	N/A
MATRIX MEDICAL CORP	Small	N/A
MERICON INDUSTRIES INC	Small	N/A
MIZA PHARMACEUTICALS USA INC	Small	N/A
MK LABORATORIES INC	Medium	N/A
MM MAST AND CO	Small	N/A
MONTEREY PHARMACEUTICALS LLC	Small	Small
MUSTAFA NEVZAT ILAC SAN AS	Medium	Small
NORTEC DEVELOPMENT ASSOCS INC GLATT AIR TECHNIQUES INC	Paid	Small
ONEX HEALTHCARE HOLDINGS INC	Small	N/A
OPTOPICS LABORATORIES CORP	Small	N/A
PHARMA SERVE INC SUB TORIGIAN LABORATORIES	Small	N/A
PHARMACEUTICAL SPECIALIST ASSOC	Small	N/A
PHARMACEUTICAL VENTURES LTD	Small	N/A
PHARMATON LTD	Small	N/A
PHARMERAL INC	Small	Small
PHOENIX LABORATORIES INC	Small	N/A
POLYMEDICA INDUSTRIES INC	Small	Small
PREMO PHARMACEUTICAL LABORATORIES INC	Small	N/A

Parent Company Name	Program Fee Tier In Arrears	
	FY 2018	FY 2019
PRIVATE FORMULATIONS INC	Small	N/A
PROTER LABORATORY SPA	Small	N/A
REXALL DRUG CO	Small	N/A
ROUSES POINT PHARMACEUTICALS LLC	N/A	Small
SCHERER LABORATORIES INC	Small	N/A
SHIRE RICHWOOD INC	Medium	N/A
SOAPCO INC	Small	N/A
STAR PHARMACEUTICALS INC	Small	Small
SYOSSET LABORATORIES INC	Small	N/A
TABLICAPS INC	Small	N/A
TG UNITED INC	Small	Small
THERAGEN INC	Small	N/A
TRACE LIFE SCIENCES INC	Small	N/A
VALIDUS PHARMACEUTICALS LLC	Paid	Small
VANGARD LABORATORIES INC DIV MIDWAY MEDICAL CO	Small	Small
WE PHARMACEUTICALS INC	Small	N/A
WENDT LABORATORIES INC	Medium	N/A
WRASER PHARMACEUTICALS LLC	Paid	Small
XANODYNE PHARMACAL INC	Small	N/A
XSPIRE PHARMA LLC	Small	Small
ZZEON PHARMACEUTICALS LTD	Small	N/A