

GDUFA Facility Arrears List

Thursday, June 16, 2022

The following facilities have not satisfied one or more annual facility fee(s) as required under the Generic Drug User Fee Amendments. The facility fee, incurred pursuant to § 744B(a)(4)(A)(i), was due no later than March 04, 2013 for Fiscal Year (FY) 2013, October 18, 2013 for FY 2014, October 1, 2014 for FY 2015, October 1, 2015 for FY 2016, October 3, 2016 for FY 2017, October 2, 2017 for FY 2018, October 1, 2018 for FY 2019, October 1, 2019 for FY 2020, and October 1, 2020 for FY 2021. Failure to timely submit the annual facility payment means that the Food and Drug Administration (FDA) will not be able to receive new ANDAs or PASs referencing these facilities within the meaning of § 505(j)(5)(A). The FDA will also not be able to receive applications submitted by the owners, or affiliates of the owners, of these facilities.

All facilities listed with an "N/A" status indicate that the facility paid, withdrawn from all generic drug submissions before an applicable facility fee due date, or did not incur a fee. If your records indicate that a facility fee was previously submitted, please contact CDERCollections@fda.hhs.gov and provide the following information: Facility name, DUNS, FEI number, User Fee Payment I.D. Number (PIN), and the payment method, date and amount. Additionally, if you believe that your facility is not subject to GDUFA fees, 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.

FACILITY NAME	FEI Number	Foreign or Domestic	GDUFA OPERATION										
			FY 2013	FY 2014	FY 2015	FY 2016	FY2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	
APEX PHARMACEUTICALS INC	3006719767	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF	FDF	N/A
BAXTER SA	3005468265	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
BIOPHARMA SRL	3006168707	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF	N/A
CHINA CHEMICAL AND PHARMACEUTICAL CORPORATION LTDTAINAN PLANT II	3008968334	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
Chongqing Shenghuaxi Pharmaceutical Co Ltd	3006810051	F	N/A	N/A	N/A	N/A	N/A	API	API	N/A	N/A	N/A	N/A
EI INC	3005832998	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF	FDF	FDF	N/A
Flamingo Pharmaceuticals Limited	3005636769	F	N/A	N/A	N/A	N/A	N/A	N/A	FDF	FDF	FDF	FDF	FDF
GENUS LIFESCIENCES INC	3003851100	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
GUANG'AN KINGDAY PHARMA & CHEM CO., LTD.	3009846816	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API
INTELLIPHARMACEUTICS CORP.	3006370451	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
JINAN JINDA PHARMACEUTICAL CHEMISTRY CO. LTD.	3004002973	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API	N/A

MAITHRI LABORATORIES PRIVATE LIMITED	3007800082	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API
MUNDIPHARMA GMBH	1000449371	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF	FDF	N/A
Parabolic Drugs	3007577941	F	N/A	N/A	API	API	API	N/A	N/A	N/A	N/A	N/A	N/A
PTI ROYSTON, LLC	3005372036	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
R CHEM (SOMANAHALLI) PVT LTD	3014002712	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API	API	API
SANOFI CHIMIE CENTRE DE PRODUCTION DE ROMAINVILLE	3002808028	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API	N/A	N/A	N/A
SARACA LABORATORIES LIMITED	3004641543	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API	N/A
Sharon Bio-medicine Limited	3005925733	F	FDF	FDF	FDF	FDF	FDF	N/A	N/A	N/A	N/A	N/A	N/A
STERLING PHARMACEUTICAL SERVICES, LLC	3009705561	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF	FDF
STRIVE PHARMACEUTICALS INC.	3013896178	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF	N/A
Suir Pharma Ireland	3002806637	F	N/A	N/A	N/A	N/A	FDF	FDF	FDF	FDF	FDF	N/A	N/A
UNIMARK REMEDIES LIMITED	3004414652	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API
VISTA PHARMACEUTICALS LIMITED	3003978209	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF	FDF	N/A
Yunnan Hande Bio-Tech Co., Ltd	3002808537	F	N/A	N/A	N/A	N/A	N/A	API	API	N/A	N/A	N/A	N/A
ZHEJIANG HAIZHOU PHARMACEUTICAL CO., LTD.	3002917378	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API	API