

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, October 1, 2020 for FY 2021, October 1, 2021 for FY 2022, October 3, 2022 for FY 2023, October 2, 2023 for FY 2024 and October 1, 2024 for FY2025. 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All facilities listed with an “N/A” status indicate that the facility paid, withdrawn from all generic drug submissions before an applicable facility fee due date, or did not incur a fee.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	FY 2023	FY 2024	FY 2025	
ALCHYMARS ICM SM PRIVATE LIMITED	3005216842	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API	N/A	API	
APEX PHARMACEUTICALS INC	3006719767	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF	FDF	FDF	FDF	N/A	N/A
APNAR PHARMA PRIVATE LIMITED	3016579947	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF	FDF	FDF
ARCH PHARMALABS LIMITED	3002808114	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API
AVARA LISCATE PHARMACEUTICAL SERVICES SPA	3004640070	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
BAJAJ MEDICAL LLC	3010164083	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
BAYER PHARMA AG	3002808084	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API
BAYER PHARMA AG	3002808063	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API
BIEFFE MEDITAL SA	3005164365	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
BIOSINT SPA	3002806601	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API	API	API	API	N/A
CAPCIUM INC.	3017663620	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF	N/A

CAPOT CHEMICAL CO., LTD	3008285194	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API	API
CENEXI	3007250542	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
CENEXI LABORATORIES THISSEN SA	3007388138	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
CHINA CHEMICAL AND PHARMACEUTICAL CORPORATION LTD TAINAN 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	N/A	N/A	N/A
CHIROGATE INTERNATIONAL INC	3006560887	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API
CISEN PHARMACEUTICAL CO.,LTD	3009982239	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF	FDF	FDF
DELPHARM LILLE SAS	3007684549	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
ECI PHARMACEUTICALS LLC	3008798439	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF	FDF	FDF
EI INC	3005832998	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF	FDF	FDF	N/A	N/A	N/A	N/A
ELYSIUM PHARMACEUTICALS LIMITED	3005183272	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
EMCURE PHARMACEUTICALS LIMITED	3005151215	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
EUROFARMA LABORATORIOS S/A	3009538725	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
EXCELVISION	3007058211	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
Flamingo Pharmaceuticals Limited	3005636769	F	N/A	N/A	N/A	N/A	N/A	N/A	FDF	FDF	FDF	FDF	FDF	FDF	FDF	N/A
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	N/A	N/A	N/A	FDF
HEBEI JIHENG (GROUP) PHARMACEUTICAL CORPORATION LTD	3004803368	F	N/A	N/A	N/A	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	FDF	FDF	FDF
INVATECH PHARMA SOLUTIONS LLC	3009964119	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
ISOTOPIA MOLECULAR IMAGING	1000234390	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
JET PULVERIZER COMPANY INC	2227260	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API
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	N/A	N/A	N/A
KINOMEGA BIOPHARM INC.	3009754809	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API	API	API	API
LIANYUNGANG KANGLE PHARMACEUTICAL CO., LTD.	3010728729	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API
MICRONISIERUNGS-KONTOR OBERROT GMBH	3005909896	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API
MITHRA PHARMACEUTICALS CDMO SA	3011415209	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
MURTY PHARMACEUTICALS INC	1000515343	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF	N/A	N/A
NATIONAL PHARMACEUTICAL INDUSTRIES CO.	3009659127	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
NOBILUS ENT ODDZIAL KUTNO	3008517755	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API
NOSTRUM LABORATORIES INC.	1518957	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
NOSTRUM LABORATORIES, INC.	1930436	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
OMEGA LABORATORIES LTD.	3004153143	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
PHARMASOL CORPORATION	1250001	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF	FDF	N/A

PROQUINA PRODUCTOS QUIMICOS NATURALESSA	3002807925	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API
PRZEDSIĘBIORSTWO PRODUKCYJNO WDROZENIOWE IFOTAM SP ZOO ZAKLA	3003022124	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API	API	API
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	N/A	N/A	N/A
R.L. FINE CHEM PRIVATE LIMITED	3005560263	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API
RAYBOW USA INC.	3004872718	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API
RIVOPHARM SA	3005884589	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
SAMCHUNDANG PHARM CO, LTD	3008425092	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
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	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	N/A	N/A	N/A
Sharon Bio-medicine Limited	3005925733	F	FDF	FDF	FDF	FDF	FDF	FDF	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
STASON PHARMACEUTICALS INC	1000160561	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
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	FDF	FDF	FDF
Suir Pharma Ireland	3002806637	F	N/A	N/A	N/A	N/A	FDF	FDF	FDF	FDF	N/A	N/A	N/A	N/A	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	API	N/A	API
VALENS MOLECULES PRIVATE LIMITED	3003802255	F	N/A	N/A	N/A	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	FDF	FDF	FDF	FDF

VITALIFE LABORATORIES (A DIV OF ARCH PHARMALABS LTD)	3005674618	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API
WINDER LABORATORIES LLC	3008694072	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF
WOCKHARDT LIMITED	3005289335	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF	N/A	N/A
YANGZHOU PHARMACEUTICAL CORPORATION LTD	3004026935	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API
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	N/A	N/A