GDUFA Facility Arrears List

Tuesday, November 17, 2026

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, October 1, 2024 for FY2025, November 13, 2025 for FY2026 and October 1, 2026 for FY2027. 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All facilities listed with an "N/A" status indicate that the facility paid, withdrawn from all generic drug submissions before an applicable facility fee due date, or did not incur a fee.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 FDAUserFees@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 FDAUserFees@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.

*** All fiscal year columns reflect GDUFA operation type.**

FACILITY NAME	FEI Number	Foreign or Domestic	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
2Y-BIOPHARMA, LTD.	3024771353	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	N/A	FDF
ACTAVIS PHARMA, INC.	3003937591	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	N/A	FDF
AJINOMOTO OMNICHEM NV	3002807802	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	N/A	API
ALCAMI CAROLINAS CORPORATION	1000158582	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	N/A	FDF
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	N/A	N/A	N/A	API	API
AMERICAN INJECTABLES, INC.	3017511577	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	N/A	FDF
APEX PHARMACEUTICALS INC	3006719767	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF	FDF	FDF	FDF	N/A	N/A	N/A	N/A
APNAR PHARMA LLP	3011136472	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	FDF
APTAPHARMA INC.	3010164738	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	N/A	FDF
AQVIDA GMBH	3017440477	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	N/A	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	N/A	API
ASOLUTION PHARMACEUTICAL PRIVATE LIMITED	3013999816	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	N/A	API
ASTREA FONTAINE	3002807473	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	FDF

FACILITY NAME	FEI Number	Foreign or Domestic	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
AURORIUM LLC	1628757	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	N/A	API
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	FDF	FDF	N/A	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	FDF	N/A	N/A	N/A	N/A	N/A
CIRON DRUGS AND PHARMACEUTICALS PVT LTD	3017545500	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	N/A	FDF
CIT SRL	1000190495	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	N/A	FDF
CORDEN PHARMA CHENOVE	3002808295	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	N/A	API
DIPHARMA INC.	3004853226	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	N/A	API
DZD (HEZE) PHARMACEUTICAL CO., LTD.	3012104330	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	N/A	API
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	FDF	FDF	FDF	FDF	N/A
EI INC	3005832998	D	N/A	N/A	N/A	N/A	N/A	N/A	FDF	FDF	FDF	N/A	N/A	N/A	N/A	N/A	N/A
EVEREST ORGANICS LIMITED	3008616840	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A				API
FRONTIDA BIOPHARM INC.	3008087151	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	N/A	FDF
GENUS LIFESCIENCES	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	N/A	FDF
GLATT GMBH	3004146501	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	N/A
GMFC LABS PVT LTD	3020444708	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	API
HIBROW HEALTHCARE PRIVATE LIMITED	3014930305	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	FDF

FACILITY NAME	FEI Number	Foreign or Domestic	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Horizon Pharmaceuticals , Inc.	3000718824	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	N/A	FDF
HOVIONE LIMITED	3008058822	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	N/A	API
HUBEI HUMANWELL CHENGTIAN PHARMACEUTICAL CO., LTD.	3014268531	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	N/A	API
IDT AUSTRALIA LIMITED	3000219354	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	N/A	FDF
Incepta Bioscience	3025414397	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	N/A	FDF
INNOVARE LABS PRIVATE LIMITED	3015709928	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	N/A
INVENTAA INDUSTRIES PRIVATE LIMITED	3003903069	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	N/A	API
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	N/A
Jet Pulverizer Co 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	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	API	N/A	N/A	N/A	N/A	N/A	N/A
KEMWELL BIOPHARMA PVT.LTD.	3030644880	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	N/A	FDF
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	N/A	N/A	N/A	N/A	API
Lonza Guangzhou Pharmaceutical Ltd.	3006532186	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	N/A	API
MALADI DRUGS & PHARMACEUTICALS	3005115135	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	N/A	API
MEDICAP LABORATORIES	3006370451	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	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	FDF	N/A	N/A	N/A	N/A

FACILITY NAME	FEI Number	Foreign or Domestic	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
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	FDF	N/A	N/A
OMAN PHARMACEUTICAL PRODUCTS CORPORATION LLC	3005083824	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	N/A	FDF
OP NANOPHARMA CO., LTD.	3023553777	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	N/A	FDF
PCAS	3004704673	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	N/A	API
PCAS	3003623331	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	N/A	API
PHARMACEUTICAL MANUFACTURING RESEARCH SERVICES, INC.	3004752030	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	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	FDF	FDF	N/A	N/A	N/A
PHARMATHEN INTERNATIONAL S. A.	3009961173	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	N/A	FDF
Phytex Australia Pty Ltd	3002807955	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	N/A	API
POINT BIOPHARMA USA INC.	3017226344	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	N/A	FDF
PRZEDSIEBIORSTWO 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	API	API	API	N/A	N/A
PURE SOURCE, LLC	3002754162	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	N/A	FDF
R CHEM (SOMANAHALLI) PVT LTD	3014002712	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API	API	API	N/A	N/A	N/A	N/A	N/A
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	FDF
SANOFI CHIMIE CENTRE DE PRODUCTION DE ROMAINVILLE	3002808028	F	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	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	API	N/A	N/A	N/A	N/A	N/A	N/A

FACILITY NAME	FEI Number	Foreign or Domestic	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Sharon Bio-medicine Limited	3005925733	F	FDF	FDF	FDF	FDF	FDF	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
SHARP STERILE MANUFACTURING, LLC	3012144557	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	N/A	FDF
SHIVALIK RASAYAN LIMITED	3020983424	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	N/A	API
SI GROUP, INC.	3011012288	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	N/A	API
SOURCETECH QUIMICA LTDA	1000571090	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	N/A	API
STERLING PHARMACEUTICAL SERVICES, LLC	3009705561	D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF	FDF	FDF	FDF	FDF	FDF	FDF
SYNERGENE ACTIVE INGREDIENTS PRIVATE LIMITED	3010634351	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	N/A	API
Tech Group Europe Limited	3010893867	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	N/A	FDF
TEDOR PHARMA INC.	3003855180	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	N/A	FDF
Topchem Pharmaceuticals Ltd	3006810418	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	N/A	API
TRASIS SA	3007236261	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	N/A	FDF
UNIMARK REMEDIES LIMITED	3004414652	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	API	API	N/A	API	API	API
UNIPHARM, INC	3009928224	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	N/A	FDF
VISTA PHARMACEUTICALS LIMITED	3003978209	F	N/A	N/A	N/A	N/A	N/A	N/A	N/A	FDF	FDF	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	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	N/A	FDF	FDF

FACILITY NAME	FEI Number	Foreign or Domestic	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
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	N/A	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	N/A	N/A	N/A	N/A
Zhejiang Jianfeng Pharmaceutical Co., Ltd	3003818412	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	N/A	FDF
ZHEJIANG STARRY PHARMACEUTICAL CORPORATION LTD	3007027206	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	N/A	API
ZHONGFU PHARMACEUTICAL CO., LTD.	3002808105	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	API