

GDUFA Facility Arrears List

Tuesday, March 31, 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 AND November 13, 2025 for FY2026. 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All facilities listed with an “N/A” status indicate that the facility paid, withdrawn from all generic drug submissions before an applicable facility fee due date, or did not incur a fee.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	FY 2026	
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	N/A	API
ANDERSONBRECON INC.	3003015528	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
ANDERSONBRECON INC.	1421377	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	N/A
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	N/A
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	N/A
BOEHRINGER INGELHEIM PHARMA GMBH AND CO. KG	3002806556	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
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	FDF	N/A
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	FDF	N/A	N/A	N/A	N/A	N/A
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	FDF	FDF	FDF	FDF	N/A

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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	N/A
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	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	N/A
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	N/A	FDF
GENILAC VE SAGLIK URUNLERI SANAYI VE TICARET ANONIM SIRKETI FABRIKASUBESI	3015775861	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
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	N/A	FDF
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	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
INDIVIOR MANUFACTURING LLC (FORMERLY SAGENT PHARMACEUTICALS, INC.)	3005208599	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
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	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	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	N/A	N/A	N/A	N/A
LEGACY PHARMACEUTICAL PACKAGING, LLC	3004453700	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

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			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	FY 2026		
MEDICAMEN BIOTECH LIMITED	3016979924	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	
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	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	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	N/A	
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	N/A	
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	N/A	
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	N/A	
QUOTIENT SCIENCES - PHILADELPHIA, LLC	3003882011	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	N/A	API	API	API	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	
SAFECOR HEALTH, LLC	3008841077	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	
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	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	N/A	

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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	
STERIGENICS BELGIUM PETIT-RECHAIN S.A.	3002807111	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	
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	
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	
TOPHARMAN SHANDONG CO., LTD.	3010708767	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	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	API	API	N/A	API	API	
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	N/A	
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	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	N/A	
Yunnan Hande Bio-Tech Co., Ltd	3002808537	F	N/A	N/A	N/A	N/A	N/A	N/A	API	API	N/A	N/A	N/A	N/A	N/A	N/A	
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	