

# GDUFA Outstanding Facility Fees – Not on Arrears List

Friday, October 04, 2019

The following facilities have not satisfied one or more annual facility fee(s) as required under GDUFA. The facility fee, incurred pursuant to § 744B(a)(4)(A)(i)-(iii), 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, and October 2, 2017 for FY2018. These facilities are not on the arrears list because reference to the facilities was removed from all generic drug submissions. See § 744B(g)(4)(B). The obligatory facility fees, however, are still owed by the listed facilities.

If a facility listed below is referenced in a new generic drug submission before satisfying all fee obligations, the facility will again be placed on the arrears list. The Food and Drug Administration (FDA) will refuse to receive new ANDAs or PASs referencing these facilities until all outstanding fees are paid. See § 744B(g)(4)(A)(ii).

A GDUFA Operation status of “N/A” means that the facility does not owe a fee for that particular fiscal year.

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 feel that your facility is not subject to GDUFA fees, please contact CDERCollections@fda.hhs.gov and provide a brief explanation. 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
A.I.G Technologies, Inc.	3003511617	D	N/A	N/A	N/A	N/A	API	N/A	N/A
AL&S, LLC (contract mfr for Olta Pharmaceuticals Corporation)	3006806161	D	N/A	N/A	API/FDF	N/A	N/A	N/A	N/A
American Antibiotics, Inc.	3005425963	D	N/A	N/A	N/A	N/A	N/A	FDF	N/A
Beijing Taiyang Pharmaceutical Industry Co., Ltd.	3003828267	F	N/A	N/A	N/A	API	API	N/A	N/A
Calaire Chimie	3002806640	F	API	API	N/A	N/A	N/A	N/A	N/A
Cambridge Major Laboratories Europe B.V.	3004153149	F	N/A	N/A	N/A	API	API	N/A	N/A
CF Pharma Ltd.	3004743234	F	N/A	N/A	API	API	API	N/A	N/A
Changzhou Siyao Pharmaceuticals Ltd	3003844102	F	N/A	N/A	N/A	N/A	FDF	N/A	N/A
CHONGQING LUMMY PHARMACEUTICAL CORPORATION LTD	3006560479	F	N/A	N/A	N/A	N/A	API	N/A	N/A
Contract Coating Inc.	2245363	D	FDF	FDF	N/A	N/A	N/A	N/A	N/A
CP Pharmaceuticals Ltd.	3003369660	F	FDF	FDF	N/A	N/A	N/A	N/A	N/A
Eczacibasi Health Products Co.	3005848494	F	FDF	FDF	FDF	N/A	N/A	N/A	N/A
Eskey Fine Chemicals (S KANT HEALTHCARE LIMITED)	3004101962	F	API	API	API	N/A	N/A	N/A	N/A

Explora Laboratories SA	3006254830	F	API	API	N/A	N/A	N/A	N/A	N/A
Gorbec Pharmaceutical Services Inc. (HATCHBEAUTY LABS, LLC )	3006405455	D	FDF	FDF	N/A	N/A	N/A	N/A	N/A
Hebei Welcome Pharmaceutical Co., Ltd.	3003030886	F	N/A	N/A	N/A	API	N/A	N/A	N/A
Julphar Gulf Pharmaceutical Industries	3004504829	F	N/A	N/A	N/A	N/A	FDF	N/A	N/A
Kyongbo Pharmaceutical Co., Ltd.	3003773799	F	N/A	N/A	API	N/A	N/A	N/A	N/A
Laboratorios Haymann S.A.	3004000118	F	API/FDF	API/FDF	N/A	N/A	N/A	N/A	N/A
LIANYUNGANG KANGLE PHARMACEUTICAL CO., LTD.	3010728729	F	N/A	N/A	N/A	N/A	N/A	API	N/A
Liaoning Chengda Biotechnology Co., Ltd.	3009810114	F	N/A	FDF	N/A	N/A	N/A	N/A	N/A
Marck Biosciences Limited	3006257565	F	FDF	FDF	FDF	N/A	N/A	N/A	N/A
N.V. Organon	3002806821	F	N/A	API	N/A	N/A	N/A	N/A	N/A
Nanjing Pharmaceutical Factory Co., Ltd	3004674350	F	N/A	N/A	API	API	API	N/A	N/A
Orgsyn Laboratory Inc.	3006725670	D	API	API	N/A	N/A	N/A	N/A	N/A
PKU HEALTHCARE CORP., LTD (aka Southwest Synthetic Pharmaceutical Corp., Ltd.)	3003723024	F	N/A	N/A	N/A	N/A	N/A	API	N/A
Polydrug Laboratories Pvt. Ltd.	3007287078	F	API	API	API	N/A	N/A	N/A	N/A
Rx Pharma-Pack, Inc.	3010167787	D	N/A	N/A	N/A	FDF	N/A	N/A	N/A
Serum Institute of India Ltd.	3004211038	F	N/A	FDF	FDF	FDF	N/A	N/A	N/A
Shandong Luwei Pharmaceutical Co., Ltd.	3007371223	F	N/A	N/A	N/A	API	N/A	N/A	N/A
Sharon Bio-Medicine Taloja	3004455093	F	N/A	N/A	API	API	API	N/A	N/A
Smruthi Organics Limited	3004896392	F	N/A	N/A	API	N/A	N/A	N/A	N/A
SOC ETUDE RECHERCH INGENIERIE PHARMA (SERIPHARM)	3002808119	F	N/A	N/A	N/A	N/A	N/A	N/A	API

Suzhou Wanqing Pharmaceutical Co., Ltd.	3005087759	F	API/FDF	API/FDF	API/FDF	API/FDF	N/A	N/A	N/A
Tianjin Jinjin Pharmaceutical Co., Ltd.	3003316563	F	API	N/A	N/A	N/A	N/A	N/A	N/A
WUXI KAILI PHARMACEUTICAL COMPANY	3003780949	F	API	API	API	API	API	N/A	N/A
Xian Libang Pharmaceutical Co., Ltd	3006417656	F	N/A	N/A	N/A	API	N/A	N/A	N/A
Zhejiang Kangle Pharmaceutical Co., Ltd.	3003311250	F	N/A	N/A	N/A	API	API	N/A	N/A
Zhejiang Yixin Pharmaceutical Co., Ltd	3004265383	F	API	API	N/A	N/A	N/A	N/A	N/A