

GDUFA Facility Arrears List

Wednesday, July 10, 2019

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, and October 1, 2018 for FY 2019. 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All facilities listed with an “N/A” status indicate that the facility paid, withdrawn from all generic drug submissions before an applicable facility fee due date, or did not incur a fee.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
A.I.G Technologies, Inc.	3003511617	D	N/A	N/A	N/A	N/A	API	N/A	N/A
American Antibiotics, Inc.	3005425963	D	N/A	N/A	N/A	N/A	N/A	FDF	FDF
ANDAPharm	3005000348	D	N/A	N/A	FDF	FDF	FDF	FDF	FDF
Blispak Acquisition Corporation	2246505	D	N/A	N/A	N/A	FDF	FDF	FDF	FDF
CF Pharma Ltd.	3004743234	F	N/A	N/A	API	API	API	N/A	N/A
Chongqing Shenghuaxi Pharmaceutical Co Ltd	3006810051	F	N/A	N/A	N/A	N/A	API	API	N/A
CSPC WEISHENG PHARMACEUTICAL (SHIJIAZHUANG) CORPORATION LTD	3008929107	F	API	API	API	API	API	API	API
DELPHARM LILLE SAS	3007684549	F	N/A	N/A	N/A	N/A	N/A	N/A	FDF
EI INC	3005832998	D	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	FDF	FDF
FUJIAN FUKANG PHARMACEUTICAL CORPORATION LTD	3003866335	F	API	API	API	API	API	API	API
JARI PHARMACEUTICAL CORPORATION LTD	3009128843	F	N/A	N/A	N/A	N/A	N/A	N/A	API
Jiangsu ZW Pharmaceuticals Co., Ltd.	3006747805	F	API	API	API	API	API	N/A	N/A

Mustafa Nevzat Ilac Sanayii, A.S.	3004173402	F	N/A	N/A	N/A	FDF	FDF	FDF	FDF
NANTONG JINGHUA PHARMACEUTICAL CO., LTD	3003735909	F	N/A	N/A	N/A	N/A	N/A	N/A	API
Parabolic Drugs	3007577941	F	N/A	N/A	API	API	API	N/A	N/A
PKU HEALTHCARE CORP., LTD.	3003094545	F	N/A	N/A	N/A	N/A	N/A	API	API
SANOFI CHIMIE CENTRE DE PRODUCTION DE ROMAINVILLE	3002808028	F	N/A	N/A	N/A	N/A	N/A	N/A	API
Shanghai Sine Pharmaceutical Corp. LTD	3004391730	F	N/A	FDF	FDF	FDF	FDF	N/A	N/A
Sharon Bio-medicine Limited	3005925733	F	FDF	FDF	FDF	FDF	FDF	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
Suir Pharma Ireland	3002806637	F	N/A	N/A	N/A	N/A	FDF	FDF	FDF
Taizhou Taifa Pharmaceuticals Co. Ltd.	3003849542	F	N/A	N/A	N/A	N/A	API	N/A	N/A
UCB PHARMA S.A.	3003909356	F	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
Zhongfu Pharmaceutical Co. Ltd (formerly known as ShanDong Weifang Pharmaceutical Factory)	3002808105	F	API	API	API	N/A	N/A	N/A	N/A