

GDUFA Facility Arrears List

Monday, August 21, 2017

"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), 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, and October 3, 2016 for FY 2017. 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) until all outstanding fees are paid. 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", submitted a withdrawal request 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 feel 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	FY 2017
A.I.G Technologies, Inc.	3003511617	D	N/A	N/A	N/A	N/A	API
Amino Gmbh	3002806319	F	API	API	API	API	API
ANDAPharm	3005000348	D	N/A	N/A	FDF	FDF	FDF
AVA, Inc.	3008736380	D	N/A	N/A	N/A	API	N/A
Beijing Taiyang Pharmaceutical Industry Co., Ltd.	3003828267	F	N/A	N/A	N/A	API	API
Blispak Acquisition Corporation	2246505	D	N/A	N/A	N/A	FDF	FDF
Cambridge Major Laboratories Europe B.V.	3004153149	F	N/A	N/A	N/A	API	API
CF Pharma Ltd.	3004743234	F	N/A	N/A	API	API	API
Chongqing Lummy Pharmaceutical Co., Ltd.	3006560479	F	N/A	N/A	N/A	N/A	API
Chongqing Shenghuaxi Pharmaceutical Co Ltd	3006810051	F	N/A	N/A	N/A	N/A	API
Contract Packaging Resources Inc	3001779561	D	N/A	N/A	N/A	FDF	FDF
Elysium Pharmaceuticals Limited	3005183272	F	N/A	N/A	N/A	N/A	FDF
Granulation Technology, Inc.	3001236066	D	FDF	FDF	N/A	N/A	N/A
Huvepharma Italia Srl (formerly Sanofi-Aventis, S.p.A.)	3003677897	F	N/A	N/A	N/A	N/A	API
Jiangsu ZW Pharmaceuticals Co., Ltd.	3006747805	F	API	API	API	API	API
Julphar Gulf Pharmaceutical Industries	3004504829	F	N/A	N/A	N/A	N/A	FDF
Mustafa Nevzat Ilac Sanayii, A.S.	3004173402	F	N/A	N/A	N/A	FDF	FDF
Parabolic Drugs	3007577941	F	N/A	N/A	API	API	API
Purdue GMP Center LLC	3005071685	D	N/A	N/A	N/A	N/A	FDF

Roche Diagnostics GmbH	3002806559	F	N/A	N/A	N/A	N/A	API
Shanghai Sine Pharmaceutical Corp. LTD	3004391730	F	N/A	FDF	FDF	FDF	FDF
Sharon Bio-medicine Limited	3005925733	F	FDF	FDF	FDF	FDF	FDF
Sharon Bio-Medicine Taloja	3004455093	F	N/A	N/A	API	API	API
Suir Pharma Ireland	3002806637	F	N/A	N/A	N/A	N/A	FDF
Taizhou Taifa Pharmaceuticals Co. Ltd.	3003849542	F	N/A	N/A	N/A	API	API
Wuxi Kaili Pharmaceutical Company LTD.	3003780949	F	API	API	API	API	API