

### GDUFA Facility Arrears List (07/07/2015)

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 and October 1, 2014 for FY 2015. 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 AskGDUFA@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 AskGDUFA@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	GDUFA OPERATION			
		Foreign or Domestic	FY 2013	FY 2014	FY 2015
ANDAPharm	3005000348	D	N/A	N/A	FDF
Antibioticos, SA	3002806372	F	API	API	API
Avon Organics Limited	3004008607	F	N/A	N/A	API
Calaire Chimie SAS	3002806640	F	API	API	N/A
CF Pharma Ltd.	3004743234	F	N/A	N/A	API
Delavau LLC	1000135987	D	N/A	N/A	API
Eskay Fine Chemicals (S. Kant Pvt Ltd)	3004101962	F	API	API	API
Explora Laboratories SA	3006254830	F	API	API	API
E-Z-EM Canada, Inc	3002808342	F	N/A	N/A	FDF
Fleming Laboratories Limited	3007931994	F	N/A	API	API
Granules India Limited	3004097901	F	API	API	API
Hetero Labs Limited Unit III	3005406526	F	API	API	N/A
IDT Biologika GmbH	3005001757	F	N/A	N/A	FDF
Jiangsu ZW Pharmaceuticals Co., Ltd.	3006747805	F	API	API	API
Keshava Organics Pvt. Ltd.	3003677831	F	N/A	N/A	API
Liquid Quimica Mexicana, S.A. de CV	3004396466	F	N/A	N/A	API
Natrium Products Inc.	1000120310	D	API	API	API
Parabolic Drugs	3007577941	F	N/A	N/A	API
Pharmacosmos A/S	3002807874	F	API	N/A	N/A
Polydrug Laboratories Pvt. Ltd.	3007287078	F	API	API	API
Purdue GMP Center LLC	3005071685	D	N/A	N/A	FDF
Serum Institute of India Ltd.	3004211038	F	N/A	FDF	FDF
Shandong Weifang Pharmaceutical Factory Co., Ltd.	3002808105	F	API	API	API
Shanghai Sine Pharmaceutical Corp. LTD	3004391730	F	N/A	FDF	FDF
Sharon Bio-medicine Limited	3005925733	F	FDF	FDF	FDF
Sharon Bio-Medicine Taloja	3004455093	F	N/A	N/A	API
Shijiazhuang Yiling Pharmaceuticals Co., Ltd	3010205691	F	FDF	FDF	FDF
S.M. Farmaceutici Spa	3008409127	F	N/A	FDF	N/A
Smruthi Organics Limited	3004896392	F	N/A	N/A	API
Syntho Pharmaceuticals	3003407422	D	FDF	FDF	FDF
Vista Pharmaceuticals, Limited.	3003978209	F	FDF	FDF	FDF
Wuhan Wuyao Pharmaceutical Co. Ltd.	3001598425	F	N/A	API	API
Wuxi Kaili Pharmaceutical Company LTD.	3003780949	F	API	API	API
Zhejiang Gold Pharma Co., Ltd.	3006640398	F	API	API	API