GDUFA Outstanding Facility Fees – Not on Arrears List

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 and October 1, 2015 for FY 2016. 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	GDUFA OPERATION				
		Foreign or Domestic	FY 2013	FY 2014	FY 2015	FY 2016
Amri Burlington, Inc.	3002951540	D	FDF	FDF	N/A	N/A
AstraZeneca	1220331	D	FDF	FDF	N/A	N/A
Contract Coating Inc.	2245363	D	FDF	FDF	N/A	N/A
CP Pharmaceuticals Ltd.	3003369660	F	FDF	FDF	N/A	N/A
Eczacibasi Health Products Co.	3005848494	F	FDF	FDF	FDF	N/A
Eskay Fine Chemicals (S. Kant Pvt Ltd)	3004101962	F	API	API	API	N/A
Gorbec Pharmaceutical Services Inc.	3006405455	D	FDF	FDF	N/A	N/A
Laboratorios Haymann S.A.	3004000118	F	API/FDF	API/FDF	N/A	N/A
Liaoning Chengda Biotechnology Co., Ltd.	3009810114	F	N/A	FDF	FDF	N/A
Marck Biosciences Limited	3006257565	F	FDF	FDF	FDF	N/A
Natrium Products Inc.	1000120310	D	API	API	API	N/A
N.V. Organon	3002806821	F	N/A	API	N/A	N/A
Orgsyn Laboratory Inc.	3006725670	D	API	API	N/A	N/A
Patheon Puerto Rico Inc.	2650178	D	N/A	FDF	N/A	N/A
Shijiazhuang Yiling Pharmaceuticals Co., Ltd	3010205691	F	FDF	FDF	FDF	N/A
Tonira Pharma Limited	3004819795	F	API	API	API	N/A
Zenotech Laboratories Ltd.	3006763276	F	FDF	FDF	N/A	N/A
Zhejiang Yixin Pharmaceutical Co., Ltd	3004265383	F	API	API	N/A	N/A