

Attachment B

Please return this form along with the updated lists of products and establishments in Attachment B by **June 10, 2016**.

Attachment B contains lists of the products and establishments for which you were assessed fees in FY 2016. The lists include all products and/or establishments that appeared on your FY 2016 invoice issued in August 2015.

In order to appropriately fill out Attachment B, please review the "Dear Colleague letter" (DCL) attached, specifically sections II and III.

Establishment Checklist	
1.	<input type="checkbox"/> Added new sites, as appropriate
2.	<input type="checkbox"/> Removed inactive sites, as appropriate
3.	<input type="checkbox"/> Numbered all the remaining establishments

Product Checklist	
1.	<input type="checkbox"/> Reviewed all products in attachment B, compared to the three publicly available lists, i.e. Orange Book , CDER Biologics & CBER Biologics
2.	<input type="checkbox"/> Added/Deleted products, as appropriate - Notified agency per section II of DCL letter
3.	<input type="checkbox"/> Numbered all products according to corresponding establishments
4.	<input type="checkbox"/> Contacted Orange Book to discontinue CDER products as needed
5.	<input type="checkbox"/> Contacted Carla Vincent to discontinue CBER products as needed

See example on next page

Attachment B Example

CDER PRODUCTS

Billing Firm: Firm Name			1211
Owner of Products: Product Owner Name	Corresponding Est. Site Numbers		
NDA #/Prod	Trade Name/ Ingredient	Dosage Form/ Strength	
12345 1	Product 1 Active Ingredient	1&2	Injectable; subcutaneous 2,500IU/0.2ml (12,500IU/ML)
12345 2	Product 2 Active Ingredient	3	Injectable; subcutaneous 5,000IU/0.2ml (25,000IU/ML)
56789 1	Product 1 Active Ingredient	Cross out discontinued product	Tablet, Extended Release; Oral EQ 4 MG BASE
56789 2	Product 2 Active Ingredient	4	Tablet, Extended Release; Oral EQ 4 MG BASE
82101 1	<i>New Product New Product Active Ingredient</i>	2	<i>New product dosage form Strength</i>

>>>> Establishments <<<<<<

Billing Firm: Firm Name			Number Est. Sites in numerical order	1211
Split: 4	3006785051	Establishment Name 1 Establishment Address City, State, Zip Country	1	10157
Split: 2	3006785052	Establishment Name 2 Establishment Address City, State, Zip Country	2	10212
Split: 16	3002597561	Establishment Name 3 Establishment Address City, State, Zip Country	Cross out inactive site	10060
Split: 1	3006785052	Establishment Name 4 Establishment Address City, State, Zip Country	3	10192
	<i>New Est. FEI/DUINS #</i>	<i>New Establishment Name Establishment Address City, State, Zip Country</i>	4	