

## Attachment B

Please return this form along with the updated lists of products in Attachment B by **August 15, 2017**.

For instructions on how to complete Attachment B, please refer to the attached Dear Colleague letter.

### Product Checklist

1.  Reviewed all products in Attachment B and compared it to the three publicly available lists, i.e. [Prescription Drug Product List](#), [CDER Billable Biologic Product List](#) & [CBER Billable Biologic Product List](#)
2.  Added/Deleted products, as appropriate
  - Notified appropriate Agency point of contact per section II and III of DCL letter
3.  Contacted [Orange Book Staff](#) to discontinue CDER prescription products as needed
4.  Contacted [CDER User Fee Staff](#) to discontinue CDER biologic products as needed
5.  Contacted [CBER User Fee Staff](#) to discontinue CBER biologics products as needed

See examples on next page

## Attachment B Example 1 - Edit Existing Product List

### CDER PRODUCTS

**Billing Firm: Firm Name**

**Owner of Products: Product Owner Name**

*Notes for PDUFA User Fee staff*

NDA #/Prod	Trade Name/ Ingredient		Dosage Form/ Strength
12345 1	Product 1 Active Ingredient	e.g. the NDA was transferred to firm B on 07/02/2017	Injectable; subcutaneous 2,500IU/0.2ml (12,500IU/ML)
12345 2	Product 2 Active Ingredient	Gained TE code, should not be billed	Injectable; subcutaneous 5,000IU/0.2ml (25,000IU/ML)
<del>56789 1</del>	<del>Product 1 Active Ingredient</del>	<del>Cross out discontinued product</del>	<del>Tablet, Extended Release; Oral EQ 4 MG BASE</del>
56789 2	Product 2 Active Ingredient	Notes	Tablet, Extended Release; Oral EQ 4 MG BASE

## Attachment B Example 2 - Missing PDUFA Eligible Products

### CDER PRODUCTS / BIOLOGIC PRODUCTS

**Billing Firm: Firm Name**

**Owner of Products: Product Owner Name**

NDA #/Prod	Trade Name/ Ingredient	Dosage Form/ Strength	Notes for PDUFA User Fee Staff
<i>NDA 082101 / 1</i>	<i>New NDA Product New Product Active Ingredient</i>	<i>New product dosage form Strength</i>	<i>New Approval on 06/28/2017</i>
<i>BLA 163590 / 0</i>	<i>New BLA Product New Product Active Ingredient</i>	<i>New product dosage form Strength 1</i>	<i>New Approval on 07/15/2017</i>
<i>BLA 163590 / 0</i>	<i>New BLA Product New Product Active Ingredient</i>	<i>New product dosage form Strength 2</i>	<i>New Approval on 07/15/2017</i>
<i>NDA 222536 / 2</i>	<i>NDA Product Product Active Ingredient</i>	<i>Product dosage form Strength</i>	<i>Transferred from firm xxx on 04/15/2017</i>

