

## Attachment B

Please return this form along with the updated lists of products in Attachment B by **June 15, 2018**.

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 III and IV 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**

**Trade Name:** Trade Name

**Ingredient:** Active Ingredient

NDA/BLA #/Prod	Approval Date	Strength / Dosage Form	Notes for PDUFA User Fee staff
123456 / 1	03/10/2018	Injectable; subcutaneous 2,500IU/0.2ml (12,500IU/ML)	e.g. the NDA was transferred to firm B on 03/12/2018
<del>123456 / 2</del>	<del>05/15/2007</del>	<del>Injectable; subcutaneous 5,000IU/0.2ml (25,000IU/ML)</del>	<del>Gained TE code, should not be billed</del>
<del>567890 / 1</del>	<del>02/01/2014</del>	<del>Tablet, Extended Release; Oral EQ 4 MG BASE</del>	<del>Cross out discontinued product</del>
567890 / 2	02/01/2014	Tablet, Extended Release; Oral EQ 4 MG BASE	Notes

## Attachment B Example 2 - Missing PDUFA Eligible Products

### CDER PRODUCTS / BIOLOGIC PRODUCTS

**Billing Firm: Firm Name**

**Owner of Products: Product Owner Name**

NDA/BLA #/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 11/28/2017</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 02/18/2018</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 02/18/2018</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 03/20/2018</i>