

Attachment B

Please return this form along with the updated lists of products in Attachment B by **June 2, 2025.**

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

Product Checklist	
1.	<input type="checkbox"/> 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.	<input type="checkbox"/> Added/Deleted products, as appropriate <ul style="list-style-type: none">- Notified appropriate Agency point of contacts per section III and IV of DCL letter
3.	<input type="checkbox"/> Contacted Orange Book Staff to discontinue CDER prescription products as needed
4.	<input type="checkbox"/> Contacted CDER User Fee Staff to discontinue CDER biologic products as needed
5.	<input type="checkbox"/> 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 03/12/2021
<u>123456 / 2</u>	05/15/2007	Injectable; subcutaneous 5,000IU/0.2ml (25,000IU/ML)	<u>Gained TE code, should not be billed</u>
<u>567890 / 1</u>	02/01/2014	Tablet, Extended Release; Oral EQ 4 MG BASE	<u>Cross out discontinued product</u>
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 11/28/2020</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 02/18/2021</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 02/18/2021</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 03/20/2021</i>