Attachment B

Please return this form along with the updated lists of products in Attachment B by June 3, 2019.

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
~~123456 / 2~~	05/15/2007	Injectable; subcutaneous 5,000IU/0.2ml (25,000IU/ML)	~~Gained TE code, should not be billed~~
567890 / 1	~~02/01/2014~~	Tablet, Extended Release; Oral EQ 4 MG BASE	~~Cross out discontinued product~~
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
NDA 082101 / 1	*New NDA Product* *New Product Active Ingredient*	*New product dosage form* *Strength*	*New Approval on 11/28/2017*
BLA 163590 / 0	*New BLA Product* *New Product Active Ingredient*	*New product dosage form* *Strength 1*	*New Approval on 02/18/2018*
BLA 163590 / 0	*New BLA Product* *New Product Active Ingredient*	*New product dosage form* *Strength 2*	*New Approval on 02/18/2018*
NDA 222536 / 2	*NDA Product* *Product Active Ingredient*	*Product dosage form* *Strength*	*Transferred from firm xxx on 03/20/2018*

Attachment B - Missing PDUFA Eligible Products

CDER PRODUCTS / BIOLOGIC PRODUCTS

Billing Firm:

Owner of Products:

NDA/BLA #/Prod	Trade Name/ Ingredient	Dosage Form/ Strength	Notes for PDUFA User Fee Staff