

# Therapeutic Biosimilar Biological Products

This list is intended to include all user fee billable therapeutic biosimilar biological products and strengths approved under Section 351(k) of the Public Health Service Act.

Program fees are assessed for each strength in which the approved (non-revoked, non-suspended) product is manufactured in final dosage form. When evaluating the specific strength of a biosimilar biological product in final dosage form for purposes of assessing program fees for liquid parenteral biological products, this list takes into consideration both the total amount of drug substance in mass or units of activity in a product and the concentration of drug substance (mass or units of activity per unit volume of product). An auto-injector that has the same strength or potency as a prefilled syringe or vial will generally be assessed a separate biosimilar biological product program fee. In certain circumstances, products which have been discontinued from marketing but are still licensed are not assessed program fees. Those products are identified on the Discontinued Biosimilar Products Section contained herein.

The potency information contained in this list is based on information in our database. Companies are responsible for alerting the User Fee staff to any discrepancies regarding potency information. Product Number is the FDA assigned number to identify the application products. Each strength is a separate product.

The list is updated semi-annually. ( Latest Update – 2/1/2019 )

\*\*\*\*\* CDER Billable Biosimilar Product List \*\*\*\*\*

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**Applicant/License No: AMGEN INC / 1080**

**Trade Name:** MVASI

**Proper Name:** BEVACIZUMAB-AWWB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761028 / 0	1	9/14/2017	100 MG/4 ML ( 25 MG/ML ) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761028 / 0	2	9/14/2017	400 MG/16 ML ( 25 MG/ML ) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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**Applicant/License No: BOEHRINGER INGELHEIM PHARMACEUTICALS INC / 2006**

**Trade Name:** CYLTEZO

**Proper Name:** ADALIMUMAB-ADBM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761058 / 0	1	8/25/2017	40 MG/0.8 ML ( 50 MG/ML ) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

**Applicant/License No: BOEHRINGER INGELHEIM PHARMACEUTICALS INC / 2006**

761058 / 2	2	7/13/2018	20 MG/0.4 ML ( 50 MG/ML )
			SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

**Applicant/License No: CELLTRION INC / 1996**

**Trade Name:** HERZUMA

**Proper Name:** TRASTUZUMAB-PKRB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761091 / 0	1	12/14/2018	420 MG/VIAL ( 420 MG/VIAL ) POWDER / INTRAVENOUS / MULTI-DOSE VIAL

**Trade Name:** INFLECTRA

**Proper Name:** INFLIXIMAB-DYYB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125544 / 0	1	4/5/2016	100 MG ( 100 MG/VIAL ) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

**Trade Name:** TRUXIMA

**Proper Name:** RITUXIMAB-ABBS

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761088 / 0	1	11/28/2018	100 MG/10 ML ( 10 MG/ML ) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761088 / 0	2	11/28/2018	500 MG/50 ML ( 10 MG/ML ) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

**Applicant/License No: COHERUS BIOSCIENCES INC / 2023**

**Trade Name:** UNDENYCA

**Proper Name:** PEGFILGRASTIM-CBQV

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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**Applicant/License No: COHERUS BIOSCIENCES INC / 2023**

761039 / 0	1	11/2/2018	6 MG/0.6ML ( 10 MG/ML ) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
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**Applicant/License No: HOSPIRA INC, A PFIZER COMPANY / 1974****Trade Name:** NIVESTYM**Proper Name:** FILGRASTIM-AAFI

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761080 / 0	1	7/20/2018	300 MCG/0.5ML ( 600 MCG/ML ) SOLUTION / INTRAVENOUS,SUBCUTANEOUS / PREFILLED SYRINGE
761080 / 0	2	7/20/2018	480 MCG/0.8ML ( 600 MCG/ML ) SOLUTION / INTRAVENOUS,SUBCUTANEOUS / PREFILLED SYRINGE
761080 / 0	3	7/20/2018	300 MCG/ML ( 300 MCG/ML ) SOLUTION / INTRAVENOUS,SUBCUTANEOUS / SINGLE-DOSE VIAL
761080 / 0	4	7/20/2018	480 MCG/1.6 ML ( 300 MCG/ML ) SOLUTION / INTRAVENOUS,SUBCUTANEOUS / SINGLE-DOSE VIAL

**Trade Name:** RETACRIT**Proper Name:** EPOETIN ALFA-EPBX

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125545 / 0	1	5/15/2018	2000 UNITS ( 2000 UNITS/ML ) SOLUTION / INTRAVENOUS,SUBCUTANEOUS / SINGLE-DOSE VIAL
125545 / 0	2	5/15/2018	3000 UNITS ( 3000 UNITS/ML ) SOLUTION / INTRAVENOUS,SUBCUTANEOUS / SINGLE-DOSE VIAL
125545 / 0	3	5/15/2018	4000 UNITS ( 4000 UNITS/ML ) SOLUTION / INTRAVENOUS,SUBCUTANEOUS / SINGLE-DOSE VIAL
125545 / 0	4	5/15/2018	10000 UNITS ( 10000 UNITS/ML ) SOLUTION / INTRAVENOUS,SUBCUTANEOUS / SINGLE-DOSE VIAL

**Applicant/License No: HOSPIRA INC, A PFIZER COMPANY / 1974**

125545 / 0	5	5/15/2018	40000 UNITS ( 40000 UNITS/ML )
			SOLUTION / INTRAVENOUS,SUBCUTANEOUS / SINGLE-DOSE VIAL

**Applicant/License No: MYLAN GMBH / 2062**

**Trade Name:** FULPHILA

**Proper Name:** PEGFILGRASTIM-JMDB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761075 / 0	1	6/4/2018	6 MG/0.6 ML ( 10 MG/ML ) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

**Trade Name:** OGIVRI

**Proper Name:** TRASTUZUMAB-DKST

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761074 / 0	1	12/1/2017	420 MG ( 420 MG/VIAL ) POWDER / INTRAVENOUS / MULTI-DOSE VIAL

**Applicant/License No: PFIZER IRELAND PHARMACEUTICALS / 2060**

**Trade Name:** IXIFI

**Proper Name:** INFLIXIMAB-QBTX

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761072 / 0	1	12/13/2017	100 MG ( 100 MG/VIAL ) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

**Applicant/License No: SAMSUNG BIOEPIS CO LTD / 2046**

**Trade Name:** ONTRUZUMAB

**Proper Name:** TRASTUZUMAB-DTTB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761100 / 0	1	1/18/2019	150 MG ( 150 MG/VIAL ) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

**Applicant/License No: SAMSUNG BIOEPIS CO LTD / 2046**

**Trade Name:** RENFLEXIS

**Proper Name:** INFLIXIMAB-ABDA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761054 / 0	1	4/21/2017	100 MG ( 100 MG/VIAL ) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

**Applicant/License No: SANDOZ INC / 2003**

**Trade Name:** ERELZI

**Proper Name:** ETANERCEPT-SZZS

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761042 / 0	1	8/30/2016	25 MG/0.5 ML ( 50 MG/ML ) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761042 / 0	2	8/30/2016	50 MG/ML ( 50 MG/ML ) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761042 / 0	3	8/30/2016	50 MG/ML ( 50 MG/ML ) SOLUTION / SUBCUTANEOUS / PREFILLED PEN

**Trade Name:** HYRIMOZ

**Proper Name:** ADALIMUMAB-ADAZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761071 / 0	1	10/30/2018	40 MG/0.8ML ( 50 MG/ML ) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761071 / 0	2	10/30/2018	40 MG/0.8ML ( 50 MG/ML ) SOLUTION / SUBCUTANEOUS / PREFILLED PEN

**Trade Name:** ZARXIO

**Proper Name:** FILGRASTIM-SDNZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation

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**Applicant/License No: SANDOZ INC / 2003**

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125553 / 0    1            3/6/2015            300 MCG/0.5 ML ( 600 MCG/ML )  
SOLUTION / INTRAVENOUS,SUBCUTANEOUS / PREFILLED SYRINGE

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125553 / 0    2            3/6/2015            480 MCG/0.8 ML ( 600 MCG/ML )  
SOLUTION / INTRAVENOUS,SUBCUTANEOUS / PREFILLED SYRINGE

**Applicant/License No: AMGEN INC / 1080**

**Trade Name:** AMJEVITA

**Proper Name:** ADALIMUMAB-ATTO

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Discontinue Date
761024 / 0	1	9/23/2016	40 MG/0.8 ML ( 50 MG/ML ) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR	08/10/2018
761024 / 0	2	9/23/2016	40 MG/0.8 ML ( 50 MG/ML ) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	08/10/2018
761024 / 0	3	9/23/2016	20 MG/0.4 ML ( 50 MG/ML ) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	08/10/2018