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 – 5/31/2021)

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

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

Trade Name: AVSOLA

Proper Name: INFLIXIMAB-AXXQ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761086 / 0	1	12/6/2019	100 MG (100 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: KANJINTI

Proper Name: TRASTUZUMAB-ANNS

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761073 / 0	1	6/13/2019	420 MG (420 MG/VIAL) POWDER / INTRAVENOUS / MULTI-DOSE VIAL
761073 / 1	2	10/25/2019	150 MG (150 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: MVASI

Proper Name: BEVACIZUMAB-AWWB

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

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

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

Trade Name: RIABNI

Proper Name: RITUXIMAB-ARRX

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761140 / 0	1	12/17/2020	100 MG/10 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761140 / 0	2	12/17/2020	500 MG/50 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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
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 (420 MG/VIAL) POWDER / INTRAVENOUS / MULTI-DOSE VIAL

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

761091 / 1	2	5/16/2019	150 MG (150 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-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
761039 / 0	1	11/2/2018	6 MG/0.6ML (10 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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

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

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: NYVEPRIA

Proper Name: PEGFILGRASTIM-APGF

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761111 / 0	1	6/10/2020	6 MG/0.6 ML (10 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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 U/ML (2000 U/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
125545 / 0	2	5/15/2018	3000 U/ML (3000 U/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
125545 / 0	3	5/15/2018	4000 U/ML (4000 U/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
125545 / 0	4	5/15/2018	10000 U/ML (10000 U/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

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

125545 / 0	5	5/15/2018	40000 U/ML (40000 U/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
125545 / 5	6	6/30/2020	20000 U/2ML (10000 U/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL
125545 / 5	7	6/30/2020	20000 U/ML (20000 U/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL

Applicant/License No: **MYLAN PHARMACEUTICALS INC / 2210**

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: HULIO

Proper Name: ADALIMUMAB-FKJP

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761154 / 0	1	7/6/2020	40 MG/0.8ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761154 / 0	2	7/6/2020	40 MG/0.8 ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761154 / 0	3	7/6/2020	20 MG/0.4 ML (50 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

Applicant/License No: **MYLAN PHARMACEUTICALS INC / 2210**

761074 / 0	1	12/1/2017	420 MG (420 MG/VIAL) POWDER / INTRAVENOUS / MULTI-DOSE VIAL
761074 / 4	2	4/17/2019	150 MG (150 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **PFIZER INC / 2001**

Trade Name: ABRILADA

Proper Name: ADALIMUMAB-AFZB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761118 / 0	1	11/15/2019	40 MG/0.8ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
761118 / 0	2	11/15/2019	40 MG/0.8 ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761118 / 0	3	11/15/2019	20 MG/0.4 ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761118 / 0	4	11/15/2019	10 MG/0.2 ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: ZIRABEV

Proper Name: BEVACIZUMAB-BVZR

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761099 / 0	1	6/27/2019	100 MG/4 ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761099 / 0	2	6/27/2019	400 MG/16 ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

Trade Name: RUXIENCE

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

Proper Name: RITUXIMAB-PVVR

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761103 / 0	1	7/23/2019	100 MG/10 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761103 / 0	2	7/23/2019	500 MG/50 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: TRAZIMERA

Proper Name: TRASTUZUMAB-QYYP

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761081 / 0	1	3/11/2019	420 MG (420 MG/VIAL) POWDER / INTRAVENOUS / MULTI-DOSE VIAL
761081 / 0	2	11/30/2020	150 MG (150 MG/VIAL) POWDER / INTRAVENOUS / MULTI-DOSE VIAL

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

Trade Name: ETICOVO

Proper Name: ETANERCEPT-YKRO

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761066 / 0	1	4/25/2019	25 MG/0.5 ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761066 / 0	2	4/25/2019	50 MG/ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: HADLIMA

Proper Name: ADALIMUMAB-BWWD

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

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

761059 / 0	1	7/23/2019	40 MG/0.8 ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761059 / 0	2	7/23/2019	40 MG/0.8ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: ONTRUZANT

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
761100 / 5	2	3/19/2020	420 MG (420 MG/VIAL) POWDER / INTRAVENOUS / MULTI-DOSE VIAL

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

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

761042 / 0	3	8/30/2016	50 MG/ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-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 / AUTOINJECTOR-PREFILLED PEN

Trade Name: ZARXIO

Proper Name: FILGRASTIM-SDNZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125553 / 0	1	3/6/2015	300 MCG/0.5 ML (600 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125553 / 0	2	3/6/2015	480 MCG/0.8 ML (600 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: ZIEXTENZO

Proper Name: PEGFILGRASTIM-BMEZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761045 / 0	1	11/4/2019	6 MG/0.6ML (10 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

********** CDER Discontinued Biosimilar Product List **********

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-PREFILLED PEN	8/10/2018
761024 / 0	2	9/23/2016	40 MG/0.8 ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	8/10/2018
761024 / 0	3	9/23/2016	20 MG/0.4 ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	8/10/2018

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	Discontinue Date
761072 / 0	1	12/13/2017	100 MG (100 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	9/13/2019