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 – August 2023)

********** CDER Billable 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
761024 / 0	1	9/23/2016	40 MG/0.8 ML (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761024 / 0	2	9/23/2016	40 MG/0.8 ML (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761024 / 0	3	9/23/2016	20 MG/0.4 ML (20 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761024 / 01	4	4/6/2023	10 MG/0.2 ML (10 MG/0.2 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: AVSOLA

Proper Name: INFLIXIMAB-AXXQ

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

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

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
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: **AMNEAL PHARMACEUTICALS LLC / 2241**

Trade Name: ALYMSYS

Applicant/License No: **AMNEAL PHARMACEUTICALS LLC / 2241**

Proper Name: BEVACIZUMAB-MALY

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761231 / 0	1	4/13/2022	100 MG/4 ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761231 / 0	2	4/13/2022	400 MG/16 ML (25 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 (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761058 / 2	2	7/13/2018	20 MG/0.4 ML (20 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761058 / 3	3	3/18/2022	10 MG/0.2 ML (10 MG/0.2 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761058 / 16	4	5/18/2023	40 MG/0.8 ML (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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/VIAL (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

Trade Name: VEGZELMA

Proper Name: BEVACIZUMAB-ADCD

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761268 / 0	1	9/27/2022	100 MG/4 ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761268 / 0	2	9/27/2022	400 MG/16 ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: YUFLYMA

Proper Name: ADALIMUMAB-AATY

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

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

761219 / 0	1	5/23/2023	40 MG/0.4 ML (40 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761219 / 0	2	5/23/2023	40 MG/0.4 ML (40 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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

Trade Name: CIMERLI

Proper Name: RANIBIZUMAB-EQRN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761165 / 0	1	8/2/2022	0.3 MG/0.05 ML (0.3 MG/0.05 ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL
761165 / 0	2	8/2/2022	0.5 MG/0.05 ML (0.5 MG/0.05 ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL

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/0.6 ML (6 MG/0.6 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761039 / 01	2	3/3/2023	6 MG/0.6 ML (6 MG/0.6 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: YUSIMRY

Proper Name: ADALIMUMAB-AQVH

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761216 / 0	1	12/17/2021	40 MG/0.8 ML (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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

761216 / 1	2	2/27/2023	40 MG/0.8 ML (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: **ELI LILLY AND CO / 1891**

Trade Name: REZVOGLAR

Proper Name: INSULIN GLARGINE-AGLR

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761215 / 0	1	12/17/2021	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: **FRESENIUS KABI USA LLC / 2146**

Trade Name: IDACIO

Proper Name: ADALIMUMAB-AACF

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761255 / 0	1	12/13/2022	40 MG/0.8 ML (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761255 / 0	2	12/13/2022	40 MG/0.8 ML (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: STIMUFEND

Proper Name: PEGFILGRASTIM-FPGK

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761173 / 0	1	9/1/2022	6 MG/0.6 ML (6 MG/0.6 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/0.5 ML (300 MCG/0.5 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
761080 / 0	2	7/20/2018	480 MCG/0.8 ML (480 MCG/0.8 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 (6 MG/0.6 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/2 ML (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: **KASHIV BIOSCIENCES LLC / 2131**

Trade Name: FYLNETRA

Proper Name: PEGFILGRASTIM-PBBK

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761084 / 0	1	5/26/2022	6 MG/0.6 ML (6 MG/0.6 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: RELEUKO

Proper Name: FILGRASTIM-AYOW

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761082 / 0	1	2/25/2022	300 MCG/ML (300 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
761082 / 0	2	2/25/2022	480 MCG/1.6 ML (300 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
761082 / 0	3	2/25/2022	300 MCG/0.5 ML (300 MCG/0.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761082 / 0	4	2/25/2022	480 MCG/0.8 ML (480 MCG/0.8 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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

Trade Name: FULPHILA

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

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 (6 MG/0.6 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/0.8 ML (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761154 / 0	2	7/6/2020	40 MG/0.8 ML (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761154 / 0	3	7/6/2020	20 MG/0.4 ML (20 MG/0.4 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
761074 / 4	2	4/17/2019	150 MG (150 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: SEMGLEE

Proper Name: INSULIN GLARGINE-YFGN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761201 / 0	1	7/28/2021	1000 UNITS/10 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL

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

761201 / 0	2	7/28/2021	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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/0.8 ML (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
761118 / 0	2	11/15/2019	40 MG/0.8 ML (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761118 / 0	3	11/15/2019	20 MG/0.4 ML (20 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761118 / 0	4	11/15/2019	10 MG/0.2 ML (10 MG/0.2 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

Proper Name: RITUXIMAB-PVVR

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

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

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: BYOOVIZ

Proper Name: RANIBIZUMAB-NUNA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) / Dosage Form/Route/Presentation
761202 / 0	1	9/17/2021	0.5 MG/0.05 ML (0.5 MG/0.05 ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL

Trade Name: HADLIMA

Proper Name: ADALIMUMAB-BWWD

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) / Dosage Form/Route/Presentation
761059 / 0	1	7/23/2019	40 MG/0.8 ML (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761059 / 0	2	7/23/2019	40 MG/0.8 ML (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE

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

761059 / 5	3	8/15/2022	40 MG/0.4 ML (40 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761059 / 5	4	8/15/2022	40 MG/0.4 ML (40 MG/0.4 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: 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/0.8 ML (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761071 / 0	2	10/30/2018	40 MG/0.8 ML (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

761071 / 0	3	3/28/2022	10 MG/0.2 ML (10 MG/0.2 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761071 / 00	4	3/20/2023	20 MG/0.4 ML (20 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761071 / 01	5	3/20/2023	10 MG/0.1 ML (10 MG/0.1 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761071 / 01	6	3/20/2023	20 MG/0.2 ML (20 MG/0.2 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761071 / 01	7	3/20/2023	40 MG/0.4 ML (40 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761071 / 01	8	3/20/2023	80 MG/0.8 ML (80 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761071 / 01	9	3/20/2023	40 MG/0.4 ML (40 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761071 / 01	10	3/20/2023	80 MG/0.8 ML (80 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: ZARXIO

Proper Name: FILGRASTIM-SNDZ

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

Trade Name: ZIEXTENZO

Proper Name: PEGFILGRASTIM-BMEZ

Applicant/License No: SANDOZ INC / 2003

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

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

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

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	Discontinue Date
761066 / 0	1	4/25/2019	25 MG/0.5 ML (25 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	9/24/2021
761066 / 0	2	4/25/2019	50 MG/ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	9/24/2021

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	Discontinue Date
761042 / 0	1	8/30/2016	25 MG/0.5 ML (25 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	1/19/2023
761042 / 0	2	8/30/2016	50 MG/ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	1/19/2023
761042 / 0	3	8/30/2016	50 MG/ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	1/19/2023

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761042 / 1	4	11/10/2022	25 MG/VIAL (25 MG/VIAL) POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL	1/19/2023