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 2026)

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

Applicant/License No: **ACCORD BIOPHARMA INC / 2105**

Trade Name: ENNUMO

Proper Name: PEGFILGRASTIM-PCCG

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761147 / 0	1	5/7/2026	6 MG/0.6 ML (6 MG/0.6 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: FILKRI

Proper Name: FILGRASTIM-LAHA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761027 / 0	1	1/15/2026	300 MCG/0.5 ML (300 MCG/0.5 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
761027 / 0	2	1/15/2026	480 MCG/0.8 ML (480 MCG/0.8 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: HERCESSI

Proper Name: TRASTUZUMAB-STRF

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

Applicant/License No: **ACCORD BIOPHARMA INC / 2105**

761346 / 0	1	4/25/2024	150 MG/VIAL (150 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
761346 / 001	2	9/6/2024	420 MG/VIAL (420 MG/VIAL) POWDER / INTRAVENOUS / MULTI-DOSE VIAL

Trade Name: IMMGOLIS

Proper Name: GOLIMUMAB-SLDI

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761452 / 0	1	5/15/2026	50 MG/0.5 ML (50 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761452 / 0	2	5/15/2026	100 MG/ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: IMMGOLIS INTRI

Proper Name: GOLIMUMAB-SLDI

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761452 / 0	3	5/15/2026	50 MG/4 ML (12.5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: IMULDOSA

Proper Name: USTEKINUMAB-SRLF

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761364 / 0	1	10/10/2024	45 MG/0.5 ML (45 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761364 / 0	2	10/10/2024	90 MG/ML (90 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761364 / 0	3	10/10/2024	130 MG/26 ML (5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **ACCORD BIOPHARMA INC / 2105**

Trade Name: JUBEREQ

Proper Name: DENOSUMAB-DESU

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761424 / 0	2	10/29/2025	120 MG/1.7 ML (70 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: OSVYRTI

Proper Name: DENOSUMAB-DESU

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761424 / 0	1	10/29/2025	60 MG/ML (60 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: UDENYCA

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 / 013	2	3/3/2023	6 MG/0.6 ML (6 MG/0.6 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: UDENYCA ONBODY

Proper Name: PEGFILGRASTIM-CBQV

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761039 / 15	3	12/22/2023	6 MG/0.6 ML (6 MG/0.6 ML) SOLUTION / SUBCUTANEOUS / KIT

Applicant/License No: **ALVOTECH USA INC / 2225**

Trade Name: SELARSDI

Proper Name: USTEKINUMAB-AEKN

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

Applicant/License No: **ALVOTECH USA INC / 2225**

761343 / 0	1	4/16/2024	45 MG/0.5 ML (45 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
761343 / 0	2	4/16/2024	90 MG/ML (90 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761343 / 2	3	10/18/2024	130 MG/26 ML (5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: SIMLANDI

Proper Name: ADALIMUMAB-RYVK

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761299 / 0	1	2/23/2024	40 MG/0.4 ML (40 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761299 / 007	2	6/26/2024	20 MG/0.2 ML (20 MG/0.2 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761299 / 007	3	6/26/2024	40 MG/0.4 ML (40 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761299 / 007	4	6/26/2024	80 MG/0.8 ML (80 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761299 / 016	5	2/14/2025	80 MG/0.8 ML (80 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

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

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 / 011	4	4/6/2023	10 MG/0.2 ML (10 MG/0.2 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761024 / 015	5	8/14/2023	80 MG/0.8 ML (80 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761024 / 015	6	8/14/2023	40 MG/0.4 ML (40 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761024 / 015	7	8/14/2023	80 MG/0.8 ML (80 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761024 / 015	8	8/14/2023	40 MG/0.4 ML (40 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761024 / 015	9	8/14/2023	20 MG/0.2 ML (20 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
761086 / 0	1	12/6/2019	100 MG/VIAL (100 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: BKEMV

Proper Name: ECULIZUMAB-AEEB

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

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

761333 / 0	1	5/28/2024	300 MG/30 ML (10 MG/ML) SOLUTION / 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/VIAL (420 MG/VIAL) POWDER / INTRAVENOUS / MULTI-DOSE VIAL
761073 / 001	2	10/25/2019	150 MG/VIAL (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: PAVBLU

Proper Name: AFLIBERCEPT-AYYH

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761298 / 0	1	8/23/2024	2 MG/0.05 ML (2 MG/0.05 ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: RIABNI

Proper Name: RITUXIMAB-ARRX

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

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

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

Trade Name: WEZLANA

Proper Name: USTEKINUMAB-AUUB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761285 / 0	1	10/31/2023	45 MG/0.5 ML (45 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
761285 / 0	2	10/31/2023	90 MG/ML (90 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761285 / 001	3	12/26/2024	45 MG/0.5 ML (45 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761285 / 001	4	12/26/2024	90 MG/ML (90 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761331 / 0	1	10/31/2023	130 MG/26 ML (5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

Trade Name: ALYMSYS

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

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

761231 / 0	2	4/13/2022	400 MG/16 ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: BONCRESA

Proper Name: DENOSUMAB-MOBZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761456 / 0	1	12/19/2025	60 MG/ML (60 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: OZILTUS

Proper Name: DENOSUMAB-MOBZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761457 / 0	1	12/19/2025	120 MG/1.7 ML (70 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: **BIOCON BIOLOGICS INC / 2324**

Trade Name: AUKELSO

Proper Name: DENOSUMAB-KYQQ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761436 / 0	2	9/16/2025	120 MG/1.7 ML (70 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: BOSAYA

Proper Name: DENOSUMAB-KYQQ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761436 / 0	1	9/16/2025	60 MG/ML (60 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: FULPHILA

Proper Name: PEGFILGRASTIM-JMDB

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

Applicant/License No: **BIOCON BIOLOGICS INC / 2324**

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: JOBEVNE

Proper Name: BEVACIZUMAB-NWGD

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761175 / 0	1	4/9/2025	100 MG/4 ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761175 / 0	2	4/9/2025	400 MG/16 ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: KIRSTY

Proper Name: INSULIN ASPART-XJHZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761188 / 0	1	7/15/2025	1000 UNITS/10 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL
761188 / 0	2	7/15/2025	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: **BIOCON BIOLOGICS INC / 2324**

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/VIAL (420 MG/VIAL) POWDER / INTRAVENOUS / MULTI-DOSE VIAL
761074 / 004	2	4/17/2019	150 MG/VIAL (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
761201 / 0	2	7/28/2021	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: YESAFILI

Proper Name: AFLIBERCEPT-JBVF

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761274 / 0	1	5/20/2024	2 MG/0.05 ML (2 MG/0.05 ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: YESINTEK

Proper Name: USTEKINUMAB-KFCE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761406 / 0	1	11/29/2024	45 MG/0.5 ML (45 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Applicant/License No: **BIOCON BIOLOGICS INC / 2324**

761406 / 0	2	11/29/2024	90 MG/ML (90 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761406 / 0	3	11/29/2024	130 MG/26 ML (5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **BIOGEN MA INC / 2344**

Trade Name: TOFIDENCE

Proper Name: TOCILIZUMAB-BAVI

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761354 / 0	1	9/29/2023	80 MG/4 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761354 / 0	2	9/29/2023	200 MG/10 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761354 / 0	3	9/29/2023	400 MG/20 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **BIO-THERA SOLUTIONS LTD / 2218**

Trade Name: AVZIVI

Proper Name: BEVACIZUMAB-TNJN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761198 / 0	1	12/6/2023	100 MG/4 ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761198 / 0	2	12/6/2023	400 MG/16 ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: STARJEMZA

Proper Name: USTEKINUMAB-HMNY

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

Applicant/License No: **BIO-THERA SOLUTIONS LTD / 2218**

761419 / 0	1	5/22/2025	45 MG/0.5 ML (45 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
761419 / 0	2	5/22/2025	90 MG/ML (90 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761419 / 0	3	5/22/2025	130 MG/26 ML (5 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 / 002	2	7/13/2018	20 MG/0.4 ML (20 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761058 / 011	3	3/18/2022	10 MG/0.2 ML (10 MG/0.2 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761058 / 016	4	5/18/2023	40 MG/0.8 ML (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761058 / 026	5	4/30/2024	40 MG/0.4 ML (40 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761058 / 026	6	4/30/2024	40 MG/0.4 ML (40 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

Trade Name: AVTOZMA

Proper Name: TOCILIZUMAB-ANOH

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761420 / 0	1	1/24/2025	80 MG/4 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761420 / 0	2	1/24/2025	200 MG/10 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761420 / 0	3	1/24/2025	400 MG/20 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761498 / 0	1	1/21/2026	162 MG/0.9 ML (162 MG/0.9 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761498 / 0	2	1/21/2026	162 MG/0.9 ML (162 MG/0.9 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: EYDENZELT

Proper Name: AFLIBERCEPT-BOAV

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761377 / 0	1	10/2/2025	2 MG/0.05 ML (2 MG/0.05 ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL & PREFILLED SYRINGE

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
761091 / 001	2	5/16/2019	150 MG/VIAL (150 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: INFLECTRA

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

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: OMLYCLO

Proper Name: OMALIZUMAB-IGEC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761399 / 0	1	3/7/2025	75 MG/0.5 ML (75 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761399 / 0	2	3/7/2025	150 MG/ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761399 / 4	3	12/1/2025	300 MG/2 ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: OSENVELT

Proper Name: DENOSUMAB-BMWO

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761404 / 0	2	2/28/2025	120 MG/1.7 ML (70 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: STEQEYMA

Proper Name: USTEKINUMAB-STBA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761338 / 0	1	12/17/2024	45 MG/0.5 ML (45 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
761338 / 0	2	12/17/2024	90 MG/ML (90 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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

761338 / 0	3	12/17/2024	130 MG/26 ML (5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: STOBOCLO

Proper Name: DENOSUMAB-BMWO

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761404 / 0	1	2/28/2025	60 MG/ML (60 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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
761219 / 001	3	9/29/2023	80 MG/0.8 ML (80 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761219 / 001	4	9/29/2023	80 MG/0.8 ML (80 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761219 / 001	5	9/29/2023	20 MG/0.2 ML (20 MG/0.2 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **DR REDDY'S LABORATORIES S.A. / 2320**

Trade Name: ZIMRIXBY

Proper Name: RITUXIMAB-CDXX

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761376 / 0	1	7/31/2026	100 MG/10 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761376 / 0	2	7/31/2026	500 MG/50 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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: **EMERGE BIOSCIENCE PTE LTD / 2395**

Trade Name: GARZULYS

Proper Name: INSULIN ASPART-FSAN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761497 / 0	1	7/24/2026	1000 UNITS/10 ML (100 UNITS/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL
761497 / 0	2	7/24/2026	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE

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
761216 / 001	2	2/27/2023	40 MG/0.8 ML (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: **FORMYCON AG / 2322**

Trade Name: AHZANTIVE

Proper Name: AFLIBERCEPT-MRBB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761378 / 0	1	6/28/2024	2 MG/0.05 ML (2 MG/0.05 ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL & PREFILLED SYRINGE

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

Trade Name: BOMYNTRA

Proper Name: DENOSUMAB-BNHT

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

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

761398 / 0	2	3/25/2025	120 MG/1.7 ML (70 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: CONEXXENCE

Proper Name: DENOSUMAB-BNHT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761398 / 0	1	3/25/2025	60 MG/ML (60 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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 / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: OTULFI

Proper Name: USTEKINUMAB-AAUZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761379 / 0	1	9/27/2024	45 MG/0.5 ML (45 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
761379 / 0	2	9/27/2024	90 MG/ML (90 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761379 / 0	3	9/27/2024	130 MG/26 ML (5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: STIMUFEND

Proper Name: PEGFILGRASTIM-FPGK

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

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

Trade Name: TYENNE

Proper Name: TOCILIZUMAB-AAZG

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761275 / 0	1	3/5/2024	80 MG/4 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761275 / 0	2	3/5/2024	200 MG/10 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761275 / 0	3	3/5/2024	400 MG/20 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761449 / 0	1	3/14/2025	162 MG/0.9 ML (162 MG/0.9 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761449 / 0	2	3/14/2025	162 MG/0.9 ML (162 MG/0.9 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: **HIKMA PHARMACEUTICALS USA INC / 2356**

Trade Name: ENOBY

Proper Name: DENOSUMAB-QBDE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761439 / 0	1	9/26/2025	60 MG/ML (60 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: XTRENBO

Proper Name: DENOSUMAB-QBDE

Applicant/License No: **HIKMA PHARMACEUTICALS USA INC / 2356**

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761439 / 0	2	9/26/2025	120 MG/1.7 ML (70 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

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/0.5 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 UNITS/ML (2000 UNITS/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

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

125545 / 0	2	5/15/2018	3000 UNITS/ML (3000 UNITS/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
125545 / 0	3	5/15/2018	4000 UNITS/ML (4000 UNITS/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
125545 / 0	4	5/15/2018	10000 UNITS/ML (10000 UNITS/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
125545 / 0	5	5/15/2018	40000 UNITS/ML (40000 UNITS/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
125545 / 005	6	6/30/2020	20000 UNITS/2 ML (10000 UNITS/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL
125545 / 005	7	6/30/2020	20000 UNITS/ML (20000 UNITS/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

Applicant/License No: **KASHIV BIOSCIENCES LLC / 2131**

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: **LUPIN PHARMACEUTICALS INC / 2052**

Trade Name: ARMLUPEG

Proper Name: PEGFILGRASTIM-UNNE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761212 / 0	1	11/28/2025	6 MG/0.6 ML (6 MG/0.6 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: RANLUSPEC

Proper Name: RANIBIZUMAB-HKDZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761480 / 0	1	6/2/2026	0.5 MG/0.05 ML (0.5 MG/0.05 ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL & PREFILLED SYRINGE
761480 / 0	2	6/2/2026	0.3 MG/0.05 ML (0.3 MG/0.05 ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL & PREFILLED SYRINGE

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

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

761118 / 0	3	11/15/2019	20 MG/0.4 ML (20 MG/0.4 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
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/VIAL (420 MG/VIAL) POWDER / INTRAVENOUS / MULTI-DOSE VIAL
761081 / 0	2	11/30/2020	150 MG/VIAL (150 MG/VIAL) POWDER / INTRAVENOUS / MULTI-DOSE VIAL

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

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: EPYSQLI

Proper Name: ECULIZUMAB-AAGH

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761340 / 0	1	7/19/2024	300 MG/30 ML (10 MG/ML) SOLUTION / INTRAVENOUS / 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
761059 / 005	3	8/15/2022	40 MG/0.4 ML (40 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761059 / 005	4	8/15/2022	40 MG/0.4 ML (40 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761059 / 036	5	4/29/2026	80 MG/0.8 ML (80 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: ONTRUZANT

Proper Name: TRASTUZUMAB-DTTB

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761100 / 0	1	1/18/2019	150 MG/VIAL (150 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
761100 / 005	2	3/19/2020	420 MG/VIAL (420 MG/VIAL) POWDER / INTRAVENOUS / MULTI-DOSE VIAL

Trade Name: OPUVIZ

Proper Name: AFLIBERCEPT-YSZY

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761350 / 0	1	5/20/2024	2 MG/0.05 ML (2 MG/0.05 ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL

Trade Name: OSPOMYV

Proper Name: DENOSUMAB-DSSB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761392 / 0	1	2/13/2025	60 MG/ML (60 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: PYZCHIVA

Proper Name: USTEKINUMAB-TTWE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761373 / 0	1	6/28/2024	45 MG/0.5 ML (45 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
761373 / 0	2	6/28/2024	90 MG/ML (90 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761373 / 001	3	6/27/2025	45 MG/0.5 ML (45 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

761373 / 001	4	6/27/2025	90 MG/ML (90 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761425 / 0	1	6/28/2024	130 MG/26 ML (5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-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/VIAL (100 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: XBRYK

Proper Name: DENOSUMAB-DSSB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761392 / 0	2	2/13/2025	120 MG/1.7 ML (70 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

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

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: ENZEEVU

Proper Name: AFLIBERCEPT-ABZV

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761382 / 0	1	8/9/2024	2 MG/0.05 ML (2 MG/0.05 ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL & PREFILLED SYRINGE

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
761071 / 014	3	3/20/2023	80 MG/0.8 ML (80 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761071 / 006	4	3/20/2023	20 MG/0.4 ML (20 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761071 / 014	5	3/20/2023	10 MG/0.1 ML (10 MG/0.1 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761071 / 014	6	3/20/2023	20 MG/0.2 ML (20 MG/0.2 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761071 / 014	7	3/20/2023	40 MG/0.4 ML (40 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761071 / 014	8	3/20/2023	80 MG/0.8 ML (80 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761071 / 014	9	3/20/2023	40 MG/0.4 ML (40 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

Trade Name: JUBBONTI

Proper Name: DENOSUMAB-BBDZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761362 / 0	1	3/5/2024	60 MG/ML (60 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: TYRUKO

Proper Name: NATALIZUMAB-SZTN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761322 / 0	1	8/24/2023	300 MG/15 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: WYOST

Proper Name: DENOSUMAB-BBDZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761362 / 0	2	3/5/2024	120 MG/1.7 ML (70 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

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

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

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

761045 / 0	1	11/4/2019	6 MG/0.6 ML (6 MG/0.6 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **SANOFI AVENTIS US LLC / 1752**

Trade Name: MERILOG

Proper Name: INSULIN ASPART-SZJJ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761325 / 0	1	2/14/2025	1000 UNITS/10 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL

Trade Name: MERILOG SOLOSTAR

Proper Name: INSULIN ASPART-SZJJ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761325 / 0	2	2/14/2025	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: **SHANGHAI HENLIUS BIOTECH INC / 2354**

Trade Name: BILDYOS

Proper Name: DENOSUMAB-NXXP

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761444 / 0	1	8/28/2025	60 MG/ML (60 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: BILPREVDA

Proper Name: DENOSUMAB-NXXP

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761444 / 0	2	8/28/2025	120 MG/1.7 ML (70 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: POHERDY

Proper Name: PERTUZUMAB-DPZB

Applicant/License No: **SHANGHAI HENLIUS BIOTECH INC / 2354**

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761450 / 0	1	11/13/2025	420 MG/14 ML (30 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **SUNSHINE LAKE PHARMA CO LTD / 2343**

Trade Name: LANGLARA

Proper Name: INSULIN GLARGINE-ALDY

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761412 / 0	1	4/29/2026	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: **TANVEX BIOPHARMA USA INC / 2259**

Trade Name: NYPOZI

Proper Name: FILGRASTIM-TXID

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761126 / 0	1	6/28/2024	300 MCG/0.5 ML (300 MCG/0.5 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
761126 / 0	2	6/28/2024	480 MCG/0.8 ML (480 MCG/0.8 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **TEVA PHARMACEUTICALS INC / 2325**

Trade Name: PONLIMSI

Proper Name: DENOSUMAB-ADET

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761385 / 0	1	3/27/2026	60 MG/ML (60 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **ZYDUS LIFESCIENCES LTD / 2448**

Applicant/License No: **ZYDUS LIFESCIENCES LTD / 2448**

Trade Name: NUFYMCO

Proper Name: RANIBIZUMAB-LEYK

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761473 / 0	1	12/18/2025	0.5 MG/0.05 ML (0.5 MG/0.05 ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL
761473 / 0	2	12/18/2025	0.3 MG/0.05 ML (0.3 MG/0.05 ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL

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

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

Trade Name: YUFLYMA

Proper Name: ADALIMUMAB-AATY

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Discontinue Date
761219 / 0	6	10/28/2025	10 MG/0.1 ML (10 MG/0.1 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	7/20/2026

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	Discontinue Date
761118 / 0	4	11/15/2019	10 MG/0.2 ML (10 MG/0.2 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	6/28/2024

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/VIAL (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

Applicant/License No: SAMSUNG BIOEPIS CO LTD / 2046

761066 / 0	2	4/25/2019	50 MG/ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	9/24/2021
761066 / 1	3	5/3/2024	50 MG/ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	8/9/2024

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

Trade Name: ERELZI SENSOREADY PEN

Proper Name: ETANERCEPT-SZZS

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Discontinue Date
761042 / 0	3	8/30/2016	50 MG/ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	1/19/2023

Trade Name: HYRIMOZ

Proper Name: ADALIMUMAB-ADAZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Discontinue Date
761071 / 0	10	3/28/2022	10 MG/0.2 ML (10 MG/0.2 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	6/5/2024

Trade Name: ZARXIO

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

Proper Name: FILGRASTIM-SNDZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Discontinue Date
125553 / 3	3	8/9/2024	300 MCG/ML (300 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	9/27/2024
125553 / 3	4	8/9/2024	480 MCG/1.6 ML (300 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	9/27/2024