

Center for Drug Evaluation and Research

List of Licensed Biological Products with (1) Reference Product Exclusivity and (2) Biosimilarity or Interchangeability Evaluations to Date

BLA STN	PRODUCT (PROPER) NAME	PROPRIETARY NAME	DATE OF LICENSURE (mo/day/yr)	DATE OF FIRST LICENSURE (mo/day/yr)	REFERENCE PRODUCT EXCLUSIVITY EXPIRY DATE (mo/day/yr)	INTERCHANGEABLE (I)/ BIOSIMILAR (B)	WITHDRAWN
125118	abatacept	Orencia	12/23/05	NA	NA		
103575	abciximab	ReoPro	12/22/94	NA	NA		Yes
125274	abobotulinumtoxinA	Dysport	04/29/09				
125057	adalimumab	Humira	12/31/02	NA	NA		
761071	adalimumab-adaz	Hyrimoz	10/30/18			B	
761058	adalimumab-adbm	Cyltezo	08/25/17			B	
761118	adalimumab-afzb	Abrilada	11/15/19			B	
761024	adalimumab-atto	Amjevita	09/23/16			B	
761059	adalimumab-bwwd	Hadlima	07/23/19			B	
125427	ado-trastuzumab emtansine	Kadcyla	02/22/13				
125387	aflibercept	Eylea	11/18/11				
103979	agalsidase beta	Fabrazyme	04/24/03	NA	NA		
125431	albiglutide	Tanzeum	04/15/14				
017835	albumin chromated CR-51 serum	Chromalbin	02/23/76				
103293	aldesleukin	Proleukin	05/05/92	NA	NA		
103948	alemtuzumab	Campath, Lemtrada	05/07/01	NA	NA		
125141	alglucosidase alfa	Myozyme	04/28/06	NA	NA		
125291	alglucosidase alfa	Lumizyme	05/24/10				
125559	alirocumab	Praluent	07/24/15				
103172	alteplase, cathflo activase	Activase	11/13/87	NA	NA		
103950	anakinra	Kineret	11/14/01	NA	NA		
020304	aprotinin	Trasylol	12/29/93				
125513	asfotase alfa	Strensiq	10/23/15				
101063	asparaginase	Elspar	01/10/78	NA	NA		
125359	asparaginase erwinia chrysanthemi	Erwinaze	11/18/11				
761034	atezolizumab	Tecentriq	05/18/16				
761049	avelumab	Bavencio	03/23/17				
103764	basiliximab	Simulect	05/12/98	NA	NA		
103691	becaplermin	Regranex	12/16/97	NA	NA		
125288	belatacept	Nulojix	06/15/11				
125370	belimumab	Benlysta	03/09/11				
761043	belimumab	Benlysta	07/20/17				
761070	benralizumab	Fasenra	11/14/17				
020032	beractant	Survanta	07/01/91				
125085	bevacizumab	Avastin	02/26/04	NA	NA		
761028	bevacizumab-awwb	Mvasi	09/14/17			B	
761099	bevacizumab-bvzr	Zirabev	06/27/19			B	
761046	bezlotoxumab	Zinplava	10/21/16				
125557	blinatumomab	Blinicyto	12/03/14				
125388	brentuximab vedotin	Adcetris	08/19/11				
761032	brodalumab	Siliq	02/15/17				
761125	brovacizumab-dbl	Beovu	10/07/19				
761068	burosumab-twza	Crysvita	04/17/18				
761102	calaspargase pegol-mknl	Asparlas	12/20/18				
020521	calfactant	Infasurf	07/01/98				
125319	canakinumab	Ilaris	06/17/09				
761112	caplacizumab-yhdp	Cablivi	02/06/19				
103608	capromab pendetide	ProstaScint	10/28/96	NA	NA		
761097	cemiplimab-rlwc	Libtayo	09/28/18				
761094	cenegermin-bkbj	Oxervate	08/22/18				
761052	cerliponase alfa	Brineura	04/27/17				
125160	certolizumab pegol	Cimzia	04/22/08				
125084	cetuximab	Erbix	02/12/04	NA	NA		
021149	choriogonadotropin alfa	Ovidrel	09/20/00				

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017692	chorionic gonadotropin	Pregnyl	10/20/76				
017055	chorionic gonadotropin	A.P.L.	12/13/74				
017067	chorionic gonadotropin	Chorionic Gonadotropin	03/05/73				
017054	chorionic gonadotropin	Chorionic Gonadotropin	03/26/74				
017016	chorionic gonadotropin	Novarel	01/15/74				
018663	chymopapain	Chymodiactin	11/10/82				
101995	collagenase	Santyl	06/04/65	NA	NA		
125338	collagenase clostridium histolyticum	Xiaflex	02/02/10				
020162	corticotropin trifluate	Acthrel	05/23/96				
761128	crizanlizumab-tmca	Adakveo	11/15/19				
103749	daclizumab	Zenapax	12/10/97	NA	NA		Yes
761029	daclizumab	Zinbryta	05/27/16				Yes
761036	daratumumab	Darzalex	11/16/15				
103951	darbepoetin alfa	Aranesp	09/17/01	NA	NA		
103767	denileukin diftitox	Ontak	02/05/99	NA	NA		
125320	denosumab	Prolia, Xgeva	06/01/10				
021271	desirudin	lprivask	04/04/03				
125516	dinutuximab	Unituxin	03/10/15				
103532	dornase alfa	Pulmozyme	12/30/93	NA	NA		
125469	dulaglutide	Trulicity	09/18/14				
761055	dupilumab	Dupixent	03/28/17				
761069	durvalumab	Imfinzi	05/01/17				
125277	ecallantide	Kalbitor	12/01/09				
125166	eculizumab	Soliris	03/16/07	NA	NA		
761092	elapegedemase-lvlr	Revcovi	10/05/18				
125460	elosulfate alfa	Vimizim	02/14/14				
761035	elotuzumab	Empliciti	11/30/15				
761107	emapalumab-lzsg	Gamifant	11/20/18				
761083	emicizumab-kxwh	Hemlibra	11/16/17				
761137	enfortumab vedotin-efv	Padcev	12/18/19				
103234	epoetin alfa	Epogen/Procrit	06/01/89	NA	NA		
125545	epoetin alfa-epbx	Retacrit	05/15/18			B	
761119	eptinezumab-jjmr	Vyepti	02/21/20				
761077	erenumab-aooe	Aimovig	05/17/18				
103795	etanercept	Enbrel	11/02/98	NA	NA		
761042	etanercept-szsz	Erelzi	08/30/16			B	
761066	etanercept-ykro	Eticovo	04/25/19			B	
125522	evolocumab	Repatha	08/27/15				
761139	fam-trastuzumab deruxtecan-nxki	Enhertu	12/20/19				
050294	fibrinolytic and desoxyribonuclease combined [bovine], with chloramphenicol	Elastinase-Chloromycetin	04/01/64				
103353	filgrastim	Neupogen	02/20/91	NA	NA		
761080	filgrastim-aafi	Nivestym	07/20/18			B	
125553	filgrastim-sndz	Zarxio	03/06/15			B	
020378	follitropin alfa	Gonal-f	09/29/97				
021765	follitropin alfa	Gonal-f Rff	03/25/04				
021684	follitropin alfa	Gonal-f Rff Redi-Ject	05/25/04				
020582	follitropin beta	Follistim	09/29/97				
021273	follitropin beta	Follistim Aq	08/26/05				
021211	follitropin beta	Follistim Aq	03/23/04				
761089	fremanezumab-vfrm	Ajovy	09/14/18				
761063	galcanezumab-gnlm	Emgality	09/27/18				
125117	galsulfase	Naglazyme	05/31/05	NA	NA		
761060	gemtuzumab ozogamicin	Mylotarg	09/01/17				

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125327	glucarpidase	Voraxaze	01/17/12				
125289	golimumab	Simponi	04/24/09				
125433	golimumab	Simponi Aria	07/18/13				
761061	guselkumab	Tremfya	07/13/17				
021665	hyaluronidase	Amphadase	10/26/04				
021716	hyaluronidase	Hydase	10/25/05				
021859	hyaluronidase	Hylenex	12/02/05				
021640	hyaluronidase	Vitrase	05/05/04				
761065	ibalizumab-uiyk	Trogarzo	03/06/18				
125019	ibritumomab tiuxetan	Zevalin	02/19/02	NA	NA		
761025	idarucizumab	Praxbind	10/16/15				
125151	idursulfase	Elaprase	07/24/06	NA	NA		
020367	imiglucerase	Cerezyme	05/23/94				
125360	incobotulinumtoxinA	Xeomin	07/30/10				
103772	infliximab	Remicade	08/24/98	NA	NA		
761054	infliximab-abda	Renflexis	04/21/17			B	
761086	infliximab-axxq	Avsola	12/06/19			B	
125544	infliximab-dyyb	Inflectra	04/05/16			B	
761072	infliximab-qbtx	Ixifi	12/13/17			B	
761040	inotuzumab ozogamicin	Besponsa	08/17/17				
020986	insulin aspart	Novolog	02/07/00				
208751	insulin aspart	Fiasp	09/29/17				
021810	insulin aspart protamine and insulin aspart	Novolog Mix 50/50	08/26/08				
021172	insulin aspart protamine and insulin aspart	Novolog Mix 70/30	11/01/01				
203314	insulin degludec	Tresiba	09/25/15				
208583	insulin degludec	Xultophy 100/3.6	11/21/16				
203313	insulin degludec and insulin aspart	Ryzodeg 70/30	09/25/15				
021536	insulin detemir	Levemir	06/16/05				
205692	insulin glargine	Basaglar	12/16/15				
021081	insulin glargine	Lantus	04/20/00				
206538	insulin glargine	Toujeo	02/25/15				
208673	insulin glargine and lixisenatide	Soliqua 100/33	11/21/16				
021629	insulin glulisine	Apidra	04/16/04				
022472	insulin human	Afrezza	06/27/14				
018780	insulin human	Humulin R U-500 Humulin R U-100	10/28/82				
208157	insulin human	Myxredlin	06/20/19				
019938	insulin human	Novolin R	06/25/91				
018781	insulin isophane human	Humulin N	10/28/82				
019959	insulin isophane human	Novolin N	07/01/91				
019717	insulin isophane human and insulin human	Humulin 70/30	04/25/89				
019991	insulin isophane human and insulin human	Novolin 70/30	06/25/91				
020563	insulin lispro	Humalog	06/14/96				
205747	insulin lispro	Humalog	05/26/15				
209196	insulin lispro	Admelog	12/11/17				
021018	insulin lispro protamine and insulin lispro	Humalog Mix 50/50	12/22/99				

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021017	insulin lispro protamine and insulin lispro	Humalog Mix 75/25	12/22/99				
103132	interferon alfa-2b	Intron A	06/04/86	NA	NA		
103158	interferon alfa-n3	Alferon N Injection	10/10/89	NA	NA		
103628	interferon beta-1a	Avonex	05/17/96	NA	NA		
103780	interferon beta-1a	Rebif	03/07/02	NA	NA		
103471	interferon beta-1b	Betaseron	07/23/93	NA	NA		
125290	interferon beta-1b	Extavia	08/14/09				
103836	interferon gamma-1b	Actimmune	02/25/99	NA	NA		
125377	ipilimumab	Yervoy	03/25/11				
761113	isatuximab-irfc	Sarclisa	03/02/20				
125521	ixekizumab	Taltz	03/22/16				
017836	kit for iodinated I-125 albumin	Jeanatope	02/23/76				
017837	kit for iodinated I-135 albumin	Megatope	02/23/76				
017833	kit for the preparation of technetium Tc-99m albumin aggregated	Macrotec	02/23/76				
017776	kit for the preparation of technetium Tc-99m albumin aggregated	Pulmolite	11/16/76				
017881	kit for the preparation of technetium Tc-99m albumin aggregated	Draximage MAA	12/30/87				
210089	kit for the preparation of technetium Tc-99m albumin aggregated	Pulmotech MAA	03/23/20				
761090	lanadelumab-flyo	Takhzyro	08/23/18				
125058	laronidase	Aldurazyme	04/30/03	NA	NA		
208471	lixisenatide	Adlyxin	07/27/16				
761136	luspatercept-aamt	Reblozyl	11/08/19				
021839	mecasermin	Increlex	08/30/05				
021884	mecasermin rinfabate	Iplex	12/12/05				
020328	menotropins	Humegon	09/01/94				
021663	menotropins	Menopur	10/29/04				
017646	menotropins	Pergonal	08/22/75				
021047	menotropins	Repronex	08/27/99				
125526	mepolizumab	Nucala	11/04/15				
761122	mepolizumab	Nucala	06/06/19				
125164	methoxy polyethylene glycol-epoetin beta	Mircera	11/14/07	NA	NA		
125390	metreleptin	Myalept	02/24/14				
761051	mogamulizumab-kpkc	Poteligeo	08/08/18				
761104	moxetumomab pasudotox-tdfk	Lumoxiti	09/13/18				
125104	natalizumab	Tysabri	11/23/04	NA	NA		
125547	necitumumab	Portrazza	11/24/15				
125554	nivolumab	Opdivo	12/22/14				
125509	obiltoximab	Anthim	03/18/16				
125486	obinutuzumab	Gazyva	11/01/13				
761053	ocrelizumab	Ocrevus	03/28/17				
125422	ocriplasmin	Jetrea	10/17/12				
125326	ofatumumab	Arzerra	10/26/09				
761038	olaratumab	Lartruvo	10/19/16				Yes
103976	omalizumab	Xolair	06/20/03	NA	NA		
103000	onabotulinumtoxinA	Botox	12/29/89	NA	NA		
103694	oprelvekin	Neumega	11/25/97	NA	NA		Yes
125103	palifermin	Kepivance	12/15/04	NA	NA		
103770	palivizumab	Synagis	06/19/98	NA	NA		
020725	pancrelipase	Creon	04/30/09				
020580	pancrelipase	Cotazym	12/09/96				
022523	pancrelipase	Pancreaze	04/12/10				

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022175	pancrelipase	Pertzye	05/17/12				
022542	pancrelipase	Viokace	03/01/12				
022210	pancrelipase	Zenpep	08/27/09				
125147	panitumumab	Vectibix	09/27/06	NA	NA		
125511	parathyroid hormone	Natpara	01/23/15				
019818	pegademase	Adagen	03/21/90				
103411	pegaspargase	Oncaspar	02/01/94	NA	NA		
125031	pegfilgrastim	Neulasta	01/31/02	NA	NA		
761045	pegfilgrastim-bmez	Ziextenzo	11/04/19			B	
761039	pegfilgrastim-cbqv	Udenyca	11/02/18			B	
761075	pegfilgrastim-jmdb	Fulphila	06/04/18			B	
103964	peginterferon alfa-2a	Pegasys	10/16/02	NA	NA		
125083	peginterferon alfa-2a co-packaged with ribavirin	Pegasys Copegus Combination Pack	06/04/04	NA	NA		Yes
103949	peginterferon alfa-2b	Pegintron, Sylatron	01/19/01	NA	NA		
125499	peginterferon beta-1a	Plegridy	08/15/14				
125293	pegloticase	Krystexxa	09/14/10				
761079	pegvaliase-pqpz	Palynziq	05/24/18				
021106	pegvisomant	Somavert	03/25/03				
125514	pembrolizumab	Keytruda	09/04/14				
125409	pertuzumab	Perjeta	06/08/12	06/08/12	06/08/24		
761121	polatuzumab vedotin-piiq	Polivy	06/10/19				
020744	poractant alfa	Curosurf	11/18/99				
761085	prabotulinumtoxinA-xvfs	Jeuveau	02/01/19				
018263	radiolabeled albumin technetium Tc-99m albumin colloid kit	Microlite	03/25/83				
125477	ramucirumab	Cyramza	04/21/14				
125156	ranibizumab	Lucentis	06/30/06	NA	NA		
103946	rasburicase	Elitek	07/12/02	NA	NA		
761108	ravulizumab-cwvz	Ultomiris	12/21/18				
125349	raxibacumab	raxibacumab	12/14/12				
761033	reslizumab	Cinqair	03/23/16				
103786	reteplase	Retavase	10/30/96	NA	NA		
125249	rilonacept	Arcalyst	02/27/08	NA	NA		
103846	rimabotulinumtoxinB	Myobloc	12/08/00	NA	NA		
761105	risankizumab-rzaa	Skyrizi	04/23/19				
103705	rituximab	Rituxan	11/26/97	NA	NA		
761064	rituximab and hyaluronidase human	Rituxan Hycela	06/22/17				
761088	rituximab-abbs	Truxima	11/28/18			B	
761103	rituximab-pvvr	Ruxience	07/23/19			B	
125268	romiplostim	Nplate	08/22/08				
761062	romosozumab-aqqg	Evenity	04/09/19				
761115	sacituzemab govitecan-hziy	Trodelvy	04/22/20				
020772	sacosidase	Sucraid	04/09/98				
103362	sargramostim	Leukine	03/05/91	NA	NA		
761037	sarilumab	Kevzara	05/22/17				
125561	sebelipase alfa	Kanuma	12/08/15				
125504	secukinumab	Cosentyx	01/21/15				
125496	siltuximab	Sylvant	04/23/14				
021538	somatropin	Accretropin	01/23/08				
020280	somatropin	Genotropin	08/24/95				
019640	somatropin	Humatrope	03/08/87				
021148	somatropin	Norditropin	06/20/00				
020168	somatropin	Nutropin	11/17/93				
020522	somatropin	Nutropin Aq	12/29/95				

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021426	somatropin	Omnitrope	05/30/06				
019764	somatropin	Saizen	10/08/96				
020604	somatropin	Serostim	08/23/96				
019774	somatropin	Zomacton	05/25/95				
761116	tagraxofusp-erzs	Elzonris	12/21/18				
022458	taliglucerase alfa	Elelyso	05/01/12				
125294	tbo-filgrastim	Granix	08/29/12	08/29/12	08/29/24		
103909	tenecteplase	TNKase	06/02/00	NA	NA		
761143	teprotumumab-trbw	Tepezza	01/21/20				
022505	tesamorelin acetate	Egrifta Egrifta SV	11/10/10				
020898	thyrotropin alfa	Thyrogen	11/30/98				
761067	tildrakizumab-asmn	Ilumya	03/20/18				
125276	tocilizumab	Actemra	01/08/10				
125472	tocilizumab	Actemra	10/21/13				
103792	trastuzumab	Herceptin	09/25/98	NA	NA		
761106	trastuzumab and hyaluronidase-oysk	Herceptin Hylecta	02/28/19				
761073	trastuzumab-anns	Kanjinti	06/13/19			B	
761074	trastuzumab-dkst	Ogivri	12/01/17			B	
761100	trastuzumab-dttb	Ontruzant	01/18/19			B	
761091	trastuzumab-pkrb	Herzuma	12/14/18			B	
761081	trastuzumab-qyyp	Trazimera	03/11/19			B	
021289	urofollitropin	Bravelle	05/06/02				
021846	urokinase	Kinlytic	01/16/78				
125261	ustekinumab	Stelara	09/25/09				
761044	ustekinumab	Stelara	09/23/16				
125476	vedolizumab	Entyvio	05/20/14				
022575	velaglucerase alfa	Vpriv	02/26/10				
761047	vestronidase alfa-vjvk	Mepsevii	11/15/17				
125418	ziv-aflibercept	Zaltrap	08/03/12				

**Key -**

**BLA STN:** Biologic License Application Submission Tracking Number

**Product (Proper) Name:** The nonproprietary name designated by FDA for a biological product at the time of licensure under the PHS Act (section 351(a)(1)(B)(i) of the PHS Act and 21 CFR 600.3(k) of the FD&C Act).

**Proprietary Name:** Brand/Trade Name

**Date of Licensure:** The date the application was approved/licensed for marketing. Date of licensure for each application was identified through FDA records.

**Date of First Licensure:** The date from which reference product exclusivity began to run. Under 351(k)(7)(C), the date of first licensure will not be the date a particular application was licensed if that application is a subsequent application filed by the same or related sponsor of the biological product for a change (not including a modification to the structure of its previously approved biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength, or if the change is a modification to the structure of the previously approved biological product that does not result in a change in safety, purity, or potency.

FDA will generally make a determination of date of first licensure for reasons of regulatory necessity and/or at the request of the 351(a) application license holder.

The Agency will denote the date of first licensure as “not applicable” (NA) if:

- The product was licensed under 351(a) and the date it was licensed falls under any exclusion identified in 351(k)(7)(C) or
- More than 12 years (or 12 years and 6 months in the case of a product that has earned pediatric exclusivity) have passed since the date of licensure of the product, and thus any reference product exclusivity that the product may have had would have expired, thus obviating the need for a determination of whether any exclusion under 351(k)(7)(C) applies.

In such cases, a corresponding NA notation will also be placed in the next column, “Reference Product Exclusivity Expiry Date”.

**Reference Product Exclusivity Expiry Date:** The reference product exclusivity expiry date indicates (1) the date that is 12 years from the date of first licensure as described in 351(k)(7); plus (2) any pediatric exclusivity granted pursuant to section 505(A) of the FD&C Act, if applicable. The reference product exclusivity expiry date is the date on which a 351(k) application referencing the reference product may be licensed assuming it is not blocked by orphan exclusivity and otherwise meets the requirements for licensure under 351(k). To determine whether there is unexpired orphan exclusivity for an indication for which the reference product is licensed, please refer to the searchable database for Orphan Designated and/or Approved Products

(<http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/HowtoapplyforOrphanProductDesignation/default.htm>).

For the explanation of the notation “NA,” please see the definition of “Date of First Licensure” above.

**Interchangeable (I)/Biosimilar (B):** Identification of those biological products approved/licensed under 351(k) that were licensed as either interchangeable with or biosimilar to the reference product. Such products will be listed under the 351(a) BLA referenced in the 351(k) application. Biosimilarity has been demonstrated for the condition(s) of use (e.g., indication(s), dosing regimen(s)), strength(s), dosage form(s), and route(s) of administration described in the biosimilar

Center for Drug Evaluation and Research

List of Licensed Biological Products with (1) Reference Product Exclusivity and (2) Biosimilarity or Interchangeability Evaluations to Date

BLA STN	PRODUCT (PROPER) NAME	PROPRIETARY NAME	DATE OF LICENSURE (mo/day/yr)	DATE OF FIRST LICENSURE (mo/day/yr)	REFERENCE PRODUCT EXCLUSIVITY EXPIRY DATE (mo/day/yr)	INTERCHANGEABLE (I)/ BIOSIMILAR (B)	WITHDRAWN
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product's Full Prescribing Information.

**Withdrawn:** The BLA has been withdrawn or is no longer being marketed. This does not specify whether withdrawn for reasons of safety and/or effectiveness.

**Note:** The List of Licensed Biological Products with (1) Reference Product Exclusivity and (2) Biosimilarity or Interchangeability Evaluations reflects all BLAs that were active at the time the "Purple Book" was originally published on September 9, 2014. FDA will continue to update the list when FDA licenses a biological product under section 351(a) or section 351(k) of the PHS Act and/or makes a determination regarding date of first licensure for a biological product licensed under section 351(a) of the PHS Act, and to reflect other changes in the status of these biological products, as appropriate.