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FIRST LICENSURE (mo/day/yr)	REFERENCE PRODUCT EXCLUSIVITY EXPIRY DATE (mo/day/yr)	INTERCHANGEABLE (I)/ BIOSIMILAR (B)	WITHDRAWN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				
103575	abciximab	ReoPro	12/22/94	NA	NA		
125274	abobotulinumtoxinA	Dysport	04/29/09				
125057	adalimumab	Humira	12/31/02	NA	NA		
125427	ado-trastuzumab emtansine	Kadcyla	02/22/13				
125387	aflibercept	Eylea	11/18/11				
103979	agalsidase beta	Fabrazyme	04/24/03				
125431	albiglutide	Tanzeum	04/15/14				
103293	aldesleukin	Proleukin	05/05/92	NA	NA		
103948	alemtuzumab	Campath, Lemtrada	05/07/01	NA	NA		
125141	alglucosidase alfa	Myozyme	04/28/06				
125291	alglucosidase alfa	Lumizyme	05/24/10				
103172	alteplase, cathflo activase	Activase	11/13/87	NA	NA		
103950	anakinra	Kineret	11/14/01	NA	NA		
101063	asparaginase	Elspar	01/10/78	NA	NA		
125359	asparaginase erwinia chrysanthemi	Erwinaze	11/18/11				
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				
125085	bevacizumab	Avastin	02/26/04				
125557	blinatumomab	Blincyto	12/03/14				
125388	brentuximab vedotin	Adcetris	08/19/11				
125319	canakinumab	Ilaris	06/17/09				
103608	capromab pendetide	ProstaScint	10/28/96	NA	NA		
125160	certolizumab pegol	Cimzia	04/22/08				
125084	cetuximab	Erbitux	02/12/04				
125338	clostridial collagenase histolyticum	Xiaflex	02/02/10				
101995	collagenase	Santyl	06/04/65	NA	NA		
103749	daclizumab	Zenapax	12/10/97	NA	NA		Yes
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				
125516	dinutuximab	Unituxin	03/10/15				
103532	dornase alfa	Pulmozyme	12/30/93	NA	NA		
125469	dulaglutide	Trulicity	09/18/14				
125277	ecallantide	Kalbitor	12/01/09				
125166	eculizumab	Soliris	03/16/07				
125460	elosulfase alfa	Vimizim	02/14/14				
103234	epoetin alfa	Epogen/Procrit	06/01/89	NA	NA		
103795	etanercept	Enbrel	11/02/98	NA	NA		
103353	filgrastim	Neupogen	02/20/91	NA	NA		
125553	filgrastim-sndz	Zarxio	03/06/15			B	
125117	galsulfase	Naglazyme	05/31/05				
125327	glucarpidase	Voraxaze	01/17/12				
125289	golimumab	Simponi	04/24/09				
125433	golimumab injection, for IV use	Simponi Aria	07/18/13				
125019	ibritumomab tiuxetan	Zevalin	02/19/02	NA	NA		
125151	idursulfase	Elaprase	07/24/06				

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125360	incobotulinumtoxinA	Xeomin	07/30/10				
103772	infliximab	Remicade	08/24/98	NA	NA		
103132	interferon alfa-2b	Intron A	06/04/86	NA	NA		
103663	interferon alfacon-1	Infergen	10/06/97	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				
125058	laronidase	Aldurazyme	04/30/03				
125164	methoxy polyethylene glycol-epoetin beta	Mircera	11/14/07				
125390	metreleptin	Myalept	02/24/14				
125104	natalizumab	Tysabri	11/23/04				
125554	nivolumab	Opdivo	12/22/14				
125486	obinutuzumab	Gazyva	11/01/13				
125422	ocriplasmin	Jetrea	10/17/12				
125326	ofatumumab	Arzerra	10/26/09				
103976	omalizumab	Xolair	06/20/03				
103000	onabotulinumtoxinA	Botox	12/29/89	NA	NA		
103694	oprelvekin	Neumega	11/25/97	NA	NA		
125103	palifermin	Kepivance	12/15/04				
103770	palivizumab	Synagis	06/19/98	NA	NA		
125147	panitumumab	Vectibix	09/27/06				
125511	parathyroid hormone	Natpara	01/23/15				
103411	pegaspargase	Oncaspar	02/01/94	NA	NA		
125031	pegfilgrastim	Neulasta	01/31/02	NA	NA		
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				Yes
103949	peginterferon alfa-2b	PegIntron, Sylatron	01/19/01	NA	NA		
125196	peginterferon alfa-2b co-packaged with ribavirin	Pegintron/Rebetol Combo Pack	06/13/08				
125499	peginterferon beta-1a	Plegridy	08/15/14				
125293	pegloticase	Krystexxa	09/14/10				
125514	pembrolizumab	Keytruda	09/04/14				
125409	pertuzumab	Perjeta	06/08/12	06/08/12	06/08/24		
125477	ramucirumab	Cyramza	04/21/14				
125156	ranibizumab	Lucentis	06/30/06				
103946	rasburicase	Elitek	07/12/02	NA	NA		
125349	raxibacumab	raxibacumab	12/14/12				
103786	reteplase	Retavase	10/30/96	NA	NA		
125249	rilonacept	Arcalyst	02/27/08				
103846	rimabotulinumtoxinB	Myobloc	12/08/00	NA	NA		
103705	rituximab	Rituxan	11/26/97	NA	NA		
125268	romiplostim	Nplate	08/22/08				
103362	sargramostim	Leukine	03/05/91	NA	NA		
125504	secukinumab	Cosentyx	01/21/15				
125496	siltuximab	Sylvant	04/23/14				
125294	tbo-filgrastim	Granix	08/29/12	08/29/12	08/29/24		

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103909	tenecteplase	TNKase	06/02/00	NA	NA		
125276	tocilizumab	Actemra	01/08/10				
125472	tocilizumab	Actemra	10/21/13				
103792	trastuzumab	Herceptin	09/25/98	NA	NA		
125261	ustekinumab	Stelara	09/25/09				
125476	vedolizumab	Entyvio	05/20/14				
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 BLAs approved/licensed under 351(k) that were licensed as either interchangeable or biosimilar to the reference product. Such products will be listed under the reference product identified in the 351(k) application.

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.