

**Preliminary List of Approved NDAs for Biological Products
That Will Be Deemed to be BLAs on March 23, 2020
(current as of December 31, 2019)**

On March 23, 2020, an approved application for a biological product under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) shall be deemed to be a license for the biological product under section 351 of the Public Health Service Act (PHS Act) (see section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009).

To enhance transparency and facilitate planning for the March 23, 2020, transition date, FDA has compiled a preliminary list of approved applications for biological products under the FD&C Act that are listed in FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) and that will be affected by this transition provision. FDA previously described its intention to periodically update this list before the March 23, 2020, transition date. An earlier update to this preliminary list added certain administratively closed applications that are related to approved applications for biological products on the December 2018 version of this list.

The current update to the preliminary list reflects a change to the definition of “biological product” made by the Further Consolidated Appropriations Act, 2020, which was enacted on December 20, 2019. Section 605 of this Act further amended the definition of a “biological product” in section 351(i) of the PHS Act to remove the parenthetical “(except any chemically synthesized polypeptide)” from the statutory category of “protein.” Accordingly, this preliminary list has been updated to include approved NDAs for 3 chemically synthesized products that now fall within the statutory definition of a “biological product.” This updated preliminary list is current as of December 31, 2019, and additions to the list are marked with an asterisk.

The public may comment on this list by submitting a comment to the public docket established for this list and the draft guidance on “The ‘Deemed to be a License’ Provision of the BPCI Act: Questions and Answers” (Docket No. FDA-2015-D-4750). To ensure that the Agency considers any additional comments on the list before the statutory transition date, submit either electronic or written comments no later than February 19, 2020. For additional information, please refer to the Federal Register Notice of Availability for the draft guidance, available at www.regulations.gov.

Nonproprietary Name	Proprietary Name	NDA Number	NDA Holder	Initial Date of NDA Approval
aprotinin	Trasylol	020304	Bayer HealthCare Pharmaceuticals Inc.	12/29/1993
beractant	Survanta	020032	AbbVie Inc.	07/01/1991
calfactant	Infasurf	020521	ONY INC	07/01/1998
choriogonadotropin alfa	Ovidrel	021149	EMD Serono, Inc.	09/20/2000

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choriogonadotropin alfa	Pregnyl	017692	Organon USA Inc, a subsidiary of Merck & Co	10/ 20/1976
chorionic gonadotropin	A.P.L.	017055	Ferring Pharmaceuticals Inc.	12/13/1974
chorionic gonadotropin	Chorionic gonadotropin	017067	Fresenius Kabi USA, LLC	03/05/1973
chorionic gonadotropin	Chorionic Gonadotropin	017054	Bel Mar	03/26/1974
chorionic gonadotropin	Novarel	017016	Ferring Pharmaceuticals Inc.	01/15/1974
chymopapain	Chymodiactin	018663	Chart Medical Inc	11/10/1982
* corticorelin ovine triflutate	Acthrel	020162	Ferring Pharmaceuticals Inc.	05/23/1996
desirudin	lprivask	021271	Valeant Pharmaceuticals North America LLC	04/04/2003
* fibrinolysin and desoxyribonuclease combined [bovine], with chloramphenicol	Elastase-chloromycetin	050294	Pfizer, Inc.	04/01/1964
follitropin alfa	Gonal-F	020378	EMD Serono, Inc.	09/29/1997
follitropin alfa	Gonal-F RFF	021765	EMD Serono, Inc.	03/25/2004
follitropin alfa	Gonal-F RFF Redi-Ject	021684	EMD Serono, Inc.	05/25/2004

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follitropin beta	Follistim	020582	Organon USA Inc, a subsidiary of Merck & Co	09/29/1997
follitropin beta	Follistim AQ	021273	Organon USA Inc, a subsidiary of Merck & Co	08/26/2005
follicle stimulating hormone	Follistim AQ	021211	Organon USA Inc, a subsidiary of Merck & Co	03/23/2004
hyaluronidase	Amphadase	021665	Amphastar Pharmaceuticals, Inc.	10/26/2004
hyaluronidase	Hydase	021716	Akorn, Inc.	10/25/2005
hyaluronidase	Hylenex	021859	Halozyme Therapeutics, Inc.	12/02/2005
hyaluronidase	Vitrase	021640	Bausch & Lomb Incorporated	05/05/2004
imiglucerase	Cerezyme	020367	Genzyme Corporation	05/23/1994
insulin aspart	Novolog	020986	Novo Nordisk Inc.	06/07/2000
insulin aspart	Fiasp	208751	Novo Nordisk Inc.	09/29/2017
insulin aspart protamine and insulin aspart	Novolog Mix 50/50	021810	Novo Nordisk Inc.	08/26/2008

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insulin aspart protamine and insulin aspart	Novolog Mix 70/30	021172	Novo Nordisk Inc.	11/01/2001
insulin degludec	Tresiba	203314	Novo Nordisk Inc.	09/25/2015
insulin degludec and insulin aspart	Ryzodeg 70/30	203313	Novo Nordisk Inc.	09/25/2015
insulin degludec and liraglutide	Xultophy100/3 .6	208583	Novo Nordisk Inc.	11/21/2016
insulin detemir	Levemir	021536	Novo Nordisk Inc.	06/16/2005
insulin detemir	Levemir	021878	Novo Nordisk Inc.	10/19/2005
insulin glargine	Basaglar	205692	Eli Lilly and Company	12/16/2015
insulin glargine	Lantus	021081	Sanofi-Aventis US LLC	04/20/2000
insulin glargine	Toujeo	206538	Sanofi-Aventis US LLC	02/25/2015
insulin glargine and lixisenatide	Soliqua	208673	Sanofi-Aventis US LLC	11/21/2016
insulin glulisine	Apidra	021629	Sanofi-Aventis US LLC	04/16/2004
insulin human	Afrezza	022472	Mannkind Corporation	06/27/2014
insulin human	Humulin R U-500	018780	Eli Lilly and Company	10/28/1982

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	Humulin R U-100			
insulin human	Myxredlin	208157	Celerity Pharmaceuticals LLC	06/20/2019
human insulin isophane	Humulin N	018781	Eli Lilly and Company	10/28/1982
human insulin isophane and human insulin	Humulin 70/30	019717	Eli Lilly and Company	04/25/1989
NPH, human insulin isophane	Novolin N	019959	Novo Nordisk Inc.	07/01/1991
NPH, human insulin isophane and regular, human insulin	Novolin 70/30	019991	Novo Nordisk Inc.	06/25/1991
regular, human insulin	Novolin R	019938	Novo Nordisk Inc.	06/25/1991
insulin lispro	Humalog	020563	Eli Lilly and Company	06/14/1996
insulin lispro	Humalog	205747	Eli Lilly and Company	05/26/2015
insulin lispro	Admelog	209196	Sanofi-Aventis US LLC	12/11/2017

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insulin lispro protamine and insulin lispro	Humalog Mix 50/50	021018	Eli Lilly and Company	12/22/1999
insulin lispro protamine and insulin lispro	Humalog Mix 75/25	021017	Eli Lilly and Company	12/22/1999
iodinated I-125 albumin	Jeanatope	017836	ISO TEX DIAGNOSTICS INC	02/23/1976
iodinated I-131 albumin	Megatope	017837	ISO TEX DIAGNOSTICS INC	02/23/1976
albumin chromated CR-51 serum	Chromalbin	017835	ISO TEX DIAGNOSTICS INC	02/23/1976
kit for the preparation of technetium tc-99m albumin aggregated	Draximage MAA	017881	Jubilant DraxImage Inc	12/30/1987
kit for the preparation of technetium tc-99m albumin aggregated	Macrotec	017833	Bracco Diagnostics Inc.	02/23/1976
kit for the preparation of technetium tc-99m albumin aggregated	Pulmolite	017776	Jubilant Draximage Inc	11/16/1976
radiolabeled albumin technetium tc-99m albumin colloid kit	Microlite	018263	Pharmalucence Inc	03/25/1983

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* lixisenatide	Adlyxin	208471	Sanofi-Aventis US LLC	7/27/2016
mecasermin	Increlex	021839	Ipsen Biopharmaceuticals, Inc.	08/30/2005
mecasermin rinfabate	Iplex	021884	Insmed Incorporated	12/12/2005
menotropins	Humegon	020328	Organon USA Inc, a subsidiary of Merck & Co	09/01/1994
menotropins	Menopur	021663	Ferring Pharmaceuticals Inc,	10/29/2004
menotropins	Pergonal	017646	EMD Serono, Inc.	08/22/1975
menotropins	Repronex	021047	Ferring Pharmaceuticals Inc,	08/27/1999
pancrelipase	Creon	020725	AbbVie Inc.	04/30/2009
pancrelipase	Cotazym	020580	Organon USA Inc, a subsidiary of Merck & Co	12/09/1996
pancrelipase	Pancreaze	022523	Janssen Pharmaceuticals, Inc.	04/12/2010
pancrelipase	Pertzye	022175	Digestive Care, Inc.	05/17/2012
pancrelipase	Viokace	022542	Forest Laboratories, LLC	03/01/2012

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pancrelipase	Zenpep	022210	Forest Laboratories, LLC	08/27/2009
pegademase bovine	Adagen	019818	Leadiant Biosciences, Inc.	03/21/1990
pegvisomant	Somavert	021106	Pharmacia & Upjohn Company	03/25/2003
poractant alfa	Curosurf	020744	Chiesi USA, Inc.	11/18/1999
sacrosidase	Sucraid	020772	QOL Medical, LLC	04/09/1998
somatropin	Accretropin	021538	Cangene Corporation	01/23/2008
somatropin	Genotropin	020280	Pharmacia & Upjohn Company	08/24/1995
somatropin	Humatrope	019640	Eli Lilly and Company	03/08/1987
somatropin	Norditropin	021148	Novo Nordisk Inc.	06/20/2000
somatropin	Nutropin	019676	Genentech, Inc.	03/09/1994
somatropin	Nutropin	020168	Genentech, Inc.	11/17/1993
somatropin	Nutropin	020656	Genentech, Inc.	12/30/1996
somatropin	Nutropin AQ	020522	Genetech, Inc.	12/29/1995
somatropin	Omnitrope	021426	Sandoz Inc.	05/30/2006
somatropin	Saizen	019764	EMD Serono, Inc.	10/08/1996
somatropin	Serostim	020604	EMD Serono, Inc.	08/23/1996
somatropin	Zorbtive	021597	EMD Serono, Inc.	12/01/2003

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somatropin	Zomacton	019774	Ferring Pharmaceuticals Inc.	05/25/1995
taliglucerase alfa	Elelyso	022458	Pfizer Inc.	05/01/2012
* tesamorelin acetate	Egrifta SV	022505	Theratechnologies Inc.	11/10/2010
thyrotropin alfa	Thyrogen	020898	Genzyme Corporation	11/30/1998
urofollitropin	Bravelle	021484	Ferring Pharmaceuticals Inc.	12/19/2002
urofollitropin	Bravelle	021289	Ferring Pharmaceuticals Inc.	05/06/2002
urokinase	Kinlytic	021846	Microbix Biosystems Inc.	01/16/1978
velaglucerase alfa	VPRIV	022575	Shire Human Genetic Therapies, Inc.	02/26/2010