

## **List of Approved NDAs for Biological Products That Were Deemed to be BLAs on March 23, 2020**

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) was 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)(A) of the Biologics Price Competition and Innovation Act of 2009).

To enhance transparency and facilitate planning for the March 23, 2020, transition date, FDA compiled a preliminary list of approved applications for biological products under the FD&C Act that were listed in FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) and that would be affected by this transition provision. FDA posted this list on the FDA website in December 2018, and periodically updated this list before the March 23, 2020, transition date. The September 2019 update to this preliminary list added certain administratively closed applications related to approved applications for biological products that were on the December 2018 version of this list. The January 2020 update to the preliminary list reflected 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.”

FDA has provided below a list of each approved application for a biological product under the FD&C Act that was deemed to be a license (i.e., an approved biologics license application (BLA)) for the biological product on March 23, 2020. These former NDAs have been removed from FDA’s Orange Book and were added to FDA’s “Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations” on March 23, 2020. On April 2, 2020, FDA updated this list to correct an error in the listing of the names of two application holders.

| <b>Nonproprietary Name</b>    | <b>Proprietary Name</b> | <b>Former NDA Number</b> | <b>Application Holder</b>             | <b>Initial Date of NDA Approval</b> |
|-------------------------------|-------------------------|--------------------------|---------------------------------------|-------------------------------------|
| albumin chromated CR-51 serum | Chromalbin              | 017835                   | Iso-Tex Diagnostics, Inc.             | 02/23/1976                          |
| aprotinin                     | Trasylol                | 020304                   | Bayer HealthCare Pharmaceuticals Inc. | 12/29/1993                          |
| beractant                     | Survanta                | 020032                   | AbbVie Inc.                           | 07/01/1991                          |
| calfactant                    | Infasurf                | 020521                   | ONY Biotech, Inc.                     | 07/01/1998                          |
| choriogonadotropin alfa       | Ovidrel                 | 021149                   | EMD Serono, Inc.                      | 09/20/2000                          |

**List of Approved NDAs for Biological Products  
That Were Deemed to be BLAs on March 23, 2020**

| <b>Nonproprietary Name</b>  | <b>Proprietary Name</b> | <b>Former NDA Number</b> | <b>Application Holder</b>                   | <b>Initial Date of NDA Approval</b> |
|---|-------------------------|--------------------------|---|-------------------------------------|
| chorionic gonadotropin  | 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 Laboratories, Inc.                  | 03/26/1974                          |
| chorionic gonadotropin  | Novarel                 | 017016                   | Ferring Pharmaceuticals Inc.                | 01/15/1974                          |
| chymopapain   | Chymodiactin            | 018663                   | DisCure Medical, LLC                        | 11/10/1982                          |
| corticotropin ovine triflutate  | Acthrel                 | 020162                   | Ferring Pharmaceuticals, Inc.               | 05/23/1996                          |
| desirudin   | Iprivask                | 021271                   | Bausch Health US, LLC                       | 04/04/2003                          |
| fibrinolysin and desoxyribonuclease combined [bovine], with chloramphenicol | Elastase-chloromycetin  | 050294                   | Parke-Davis, a Division of Pfizer Inc.      | 04/01/1964                          |

**List of Approved NDAs for Biological Products  
That Were Deemed to be BLAs on March 23, 2020**

| <b>Nonproprietary Name</b> | <b>Proprietary Name</b>  | <b>Former NDA Number</b> | <b>Application Holder</b>                         | <b>Initial Date of NDA Approval</b> |
|----------------------------|--------------------------|--------------------------|---|-------------------------------------|
| 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<br>Redi-Ject | 021684                   | EMD Serono, Inc.                                  | 05/25/2004                          |
| follitropin beta           | Follistim                | 020582                   | Organon USA Inc,<br>a subsidiary of<br>Merck & Co | 09/29/1997                          |
| follitropin beta           | Follistim AQ             | 021273                   | Organon USA Inc,<br>a subsidiary of<br>Merck & Co | 08/26/2005                          |
| follitropin beta           | Follistim AQ             | 021211                   | Organon USA Inc,<br>a subsidiary of<br>Merck & Co | 03/23/2004                          |
| hyaluronidase              | Amphadase                | 021665                   | Amphastar<br>Pharmaceuticals,<br>Inc.             | 10/26/2004                          |
| hyaluronidase              | Hydase                   | 021716                   | Akorn, Inc.                                       | 10/25/2005                          |
| hyaluronidase              | Vitrase                  | 021640                   | Bausch & Lomb<br>Incorporated                     | 05/05/2004                          |
| hyaluronidase<br>human     | Hylenex                  | 021859                   | Halozyme<br>Therapeutics, Inc.                    | 12/02/2005                          |
| imiglucerase               | Cerezyme                 | 020367                   | Genzyme<br>Corporation                            | 05/23/1994                          |
| insulin aspart             | Novolog                  | 020986                   | Novo Nordisk Inc.                                 | 06/07/2000                          |
| insulin aspart             | Fiasp                    | 208751                   | Novo Nordisk Inc.                                 | 09/29/2017                          |

**List of Approved NDAs for Biological Products  
That Were Deemed to be BLAs on March 23, 2020**

| <b>Nonproprietary Name</b>                  | <b>Proprietary Name</b> | <b>Former NDA Number</b> | <b>Application Holder</b> | <b>Initial Date of NDA Approval</b> |
|---|-------------------------|--------------------------|---------------------------|-------------------------------------|
| insulin aspart protamine and insulin aspart | Novolog Mix 50/50       | 021810                   | Novo Nordisk Inc.         | 08/26/2008                          |
| 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            | Xultophy 100/3.6        | 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 100/33          | 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                          |

**List of Approved NDAs for Biological Products  
That Were Deemed to be BLAs on March 23, 2020**

| <b>Nonproprietary Name</b>                     | <b>Proprietary Name</b> | <b>Former NDA Number</b> | <b>Application Holder</b>        | <b>Initial Date of NDA Approval</b> |
|--|-------------------------|--------------------------|----------------------------------|-------------------------------------|
| insulin human                                  | Humulin R<br>U-500      | 018780                   | Eli Lilly and<br>Company         | 10/28/1982                          |
|  | Humulin R<br>U-100      |                          |                                  |                                     |
| insulin human                                  | Novolin R               | 019938                   | Novo Nordisk Inc.                | 06/25/1991                          |
| insulin human in<br>sodium chloride            | Myxredlin               | 208157                   | Baxter Healthcare<br>Corporation | 06/20/2019                          |
| insulin isophane<br>human                      | Humulin N               | 018781                   | Eli Lilly and<br>Company         | 10/28/1982                          |
| insulin isophane<br>human and insulin<br>human | Humulin 70/30           | 019717                   | Eli Lilly and<br>Company         | 04/25/1989                          |
| insulin isophane<br>human                      | Novolin N               | 019959                   | Novo Nordisk Inc.                | 07/01/1991                          |
| insulin isophane<br>human and insulin<br>human | Novolin 70/30           | 019991                   | Novo Nordisk Inc.                | 06/25/1991                          |
| insulin lispro                                 | Humalog                 | 020563                   | Eli Lilly and<br>Company         | 06/14/1996                          |
| insulin lispro                                 | Humalog                 | 205747                   | Eli Lilly and<br>Company         | 05/26/2015                          |
| insulin lispro                                 | Admelog                 | 209196                   | Sanofi-Aventis US<br>LLC         | 12/11/2017                          |

**List of Approved NDAs for Biological Products  
That Were Deemed to be BLAs on March 23, 2020**

| <b>Nonproprietary Name</b>                                      | <b>Proprietary Name</b> | <b>Former NDA Number</b> | <b>Application Holder</b> | <b>Initial Date of NDA Approval</b> |
|---|-------------------------|--------------------------|---------------------------|-------------------------------------|
| 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                          |
| kit for iodinated I-125 albumin                                 | Jeanatope               | 017836                   | Iso-Tex Diagnostics, Inc. | 02/23/1976                          |
| kit for iodinated I-131 albumin                                 | Megatope                | 017837                   | 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                          |
| kit for the preparation of technetium Tc-99m albumin aggregated | Pulmotech MAA           | 210089                   | CIS Bio International     | 3/20/2020                           |

**List of Approved NDAs for Biological Products  
That Were Deemed to be BLAs on March 23, 2020**

| <b>Nonproprietary Name</b> | <b>Proprietary Name</b> | <b>Former NDA Number</b> | <b>Application Holder</b>                   | <b>Initial Date of NDA Approval</b> |
|----------------------------|-------------------------|--------------------------|---|-------------------------------------|
| lixisenatide               | Adlyxin                 | 208471                   | Sanofi-Aventis US LLC                       | 7/27/2016                           |
| mecasermin                 | Increlex                | 021839                   | Ipsen Bio-pharmaceuticals, Inc.             | 08/30/2005                          |
| mecasermin<br>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                   | VIVUS Inc.                                  | 04/12/2010                          |
| pancrelipase               | Pertzye                 | 022175                   | Digestive Care, Inc.                        | 05/17/2012                          |
| pancrelipase               | Viokace                 | 022542                   | Viokace, LLC                                | 03/01/2012                          |

**List of Approved NDAs for Biological Products  
That Were Deemed to be BLAs on March 23, 2020**

| <b>Nonproprietary Name</b>                                 | <b>Proprietary Name</b> | <b>Former NDA Number</b> | <b>Application Holder</b>         | <b>Initial Date of NDA Approval</b> |
|--|-------------------------|--------------------------|-----------------------------------|-------------------------------------|
| pancrelipase   | Zenpep                  | 022210                   | Zenpep LLC                        | 08/27/2009                          |
| pegademase bovine  | Adagen                  | 019818                   | Leadiant Biosciences, Inc.        | 03/21/1990                          |
| pegvisomant  | Somavert                | 021106                   | Pharmacia & Upjohn Company LLC    | 03/25/2003                          |
| poractant alfa   | Curosurf                | 020744                   | Chiesi USA, Inc.                  | 11/18/1999                          |
| radiolabeled albumin technetium Tc-99m albumin colloid kit | Microlite               | 018263                   | Pharmalucence, Inc.               | 03/25/1983                          |
| sacrosidase  | Sucraid                 | 020772                   | QOL Medical, LLC                  | 04/09/1998                          |
| somatropin   | Accretropin             | 021538                   | Emergent BioSolutions Canada Inc. | 01/23/2008                          |
| somatropin   | Genotropin              | 020280                   | Pharmacia & Upjohn Company LLC    | 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                   | Genentech, Inc.                   | 12/29/1995                          |



**List of Approved NDAs for Biological Products  
That Were Deemed to be BLAs on March 23, 2020**

| <b>Nonproprietary Name</b> | <b>Proprietary Name</b> | <b>Former NDA Number</b> | <b>Application Holder</b>           | <b>Initial Date of NDA Approval</b> |
|----------------------------|-------------------------|--------------------------|-------------------------------------|-------------------------------------|
| 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                          |
| somatropin                 | Zomacton                | 019774                   | Ferring Pharmaceuticals, Inc.       | 05/25/1995                          |
| taliglucerase alfa         | Elelyso                 | 022458                   | Pfizer Inc.                         | 05/01/2012                          |
| tesamorelin acetate        | Egrifta and 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                          |