

**List of Withdrawn Applications for Biological Products  
That Were Removed From FDA’s Orange Book on March 23, 2020**

On March 23, 2020, the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) required that an approved application for a “biological product” under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) 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)(A) of the BPCI Act; see also section 7002(e)(4)(B)).

FDA has interpreted the statute such that an approved application under section 505 of the FD&C Act for a biological product that has been discontinued from marketing, but for which FDA has not withdrawn approval of the application, was deemed to be an approved biologics license application on March 23, 2020. However, if FDA has withdrawn approval of the application for a biological product, the application was removed from FDA’s Approved Drug Products With Therapeutic Equivalence Evaluations (the Orange Book) on March 23, 2020 and did not transition. To enhance transparency, FDA is providing the list of applications for biological products that were removed from the Orange Book on March 23, 2020.

<b>Nonproprietary Name</b>	<b>Proprietary Name</b>	<b>Former Application Number</b>	<b>Initial Date of Approval</b>	<b>Federal Register Notice of Withdrawal of Approval</b>
albumin iodinated I-125 serum	Radio-Iodinated (I 125) Serum Albumin (Human)	N017846	pre-1982	50 FR 13661 (4/5/1985)
albumin iodinated I-125 serum	Radioiodinated Serum Albumin (Human) IHSA I-125	N017844	pre-1982	74 FR 23407 (5/19/2009)
alglucerase	Ceredase	N020057	05/08/1992	77 FR 16039 (3/19/2012)
chymopapain	Discase	N018625	01/18/1984	57 FR 52782 (11/5/1992)
chymotrypsin	Catarase	N016938	pre-1982	64 FR 31226 (6/10/1999)
chymotrypsin	Alpha Chymar	N011837	pre-1982	61 FR 40649 (8/5/1996)
chymotrypsin	Catarase	N018121	pre-1982	67 FR 20977 (4/29/2002)
chymotrypsin	Zolyse	N011903	pre-1982	83 FR 7738 (2/22/2018)
cobalt chloride CO-57; cyanocobalamin; cyanocobalamin CO-57; intrinsic factor	Rubratope-57 Kit	N016089	pre-1982	82 FR 28322 (6/21/2017)
cobalt chloride CO-60; cyanocobalamin; cyanocobalamin CO-60; intrinsic factor	Rubratope-60 Kit	N016090	pre-1982	74 FR 6896 (2/11/2009)
cyanocobalamin; cyanocobalamin CO-57; intrinsic factor	Cyanocobalamin CO 57 Schilling Test Kit	N016635	pre-1982	74 FR 23407 (5/19/2009)

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fibrinogen, I-125	IBRIN	N017879	pre-1982	56 FR 43789 (9/4/1991)
fibrinogen, I-125	Radionuclide-Labeled (125 I) Fibrinogen (Human) Sensor	N017787	pre-1982	74 FR 6896 (2/11/2009)
gemtuzumab ozogamicin	Mylotarg	N021174	05/17/2000	76 FR 72955 (11/28/2011)
gonadotropin, chorionic	Follutein	N017056	pre-1982	67 FR 63107 (10/10/2002)
hyaluronidase	Wydase	N006343	pre-1982	82 FR 28322 (6/21/2017)
insulin - 70% purified pork isophane suspension and 30% purified pork insulin	Mixtard 70/30	N018195	pre-1982	64 FR 31226 (6/10/1999)
insulin – extended insulin zinc suspension (beef)	Ultralente insulin	N017997	pre-1982	62 FR 50387 (9/25/1997)
insulin – human insulin (semi-synthetic) isophane suspension	Insulatard NPH Human	N019449	03/30/1986	62 FR 50387 (9/25/1997)
insulin - lente purified pork insulin zinc suspension	Lente Purified Pork Insulin Zinc	N018383	pre-1982	68 FR 49481 (8/18/2003)
insulin – NPH human insulin isophane suspension (semi-synthetic)	Novolin N	N019065	01/23/1985	62 FR 50387 (9/25/1997)
insulin - NPH purified pork isophane insulin suspension	NPH Purified Pork Isophane Insulin	N018623	pre-1982	68 FR 49481 (8/18/2003)
insulin - NPH purified pork isophane insulin suspension	Insulatard	N018194	pre-1982	64 FR 31226 (6/10/1999)
insulin – prompt insulin zinc suspension (beef)	Semilente Insulin	N017996	pre-1982	62 FR 50387 (9/25/1997)
insulin – purified pork and beef insulin zinc suspension	Lentard	N018384	pre-1982	62 FR 50387 (9/25/1997)
insulin - regular purified pork insulin	Regular Purified Pork Insulin	N018381	pre-1982	68 FR 49481 (8/18/2003)
insulin - regular purified pork insulin	Velosulin	N018193	pre-1982	64 FR 31226 (6/10/1999)
insulin pork	Iletin I	N017931	pre-1982	74 FR 6896 (2/11/2009)
insulin pork	Insulin / Regular Insulin	N017926	pre-1982	62 FR 42575 (8/7/1997)
insulin purified beef	Regular Iletin II	N018478	pre-1982	74 FR 6896 (2/11/2009)
insulin purified pork	Iletin II	N018344	pre-1982	74 FR 6896 (2/11/2009)
insulin recombinant	Velosulin BR	N021028	07/19/1999	74 FR 6896 (2/11/2009)

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insulin recombinant human	Humulin BR	N019529	04/28/1986	74 FR 6896 (2/11/2009)
insulin recombinant human	Exubera	N021868	01/27/2006	74 FR 23407 (5/19/2009)
insulin recombinant human; insulin suspension isophane recombinant human	Humulin 50/50	N020100	04/29/1992	76 FR 33310 (6/8/2011)
insulin recombinant purified human	Novolin R	N018778	08/30/1983	61 FR 40649 (8/5/1996)
insulin recombinant purified human	Velosulin BR Human	N019450	05/30/1986	66 FR 43017 (8/16/2001)
insulin recombinant purified human; insulin suspension isophane semisynthetic purified human	Mixtard Human 70/30	N019585	03/11/1988	64 FR 31226 (6/10/1999)
insulin recombinant purified human; insulin suspension isophane semisynthetic purified human	Novolin 70/30	N019441	07/11/1986	61 FR 40649 (8/5/1996)
insulin suspension isophane beef	NPH Insulin	N017929	pre-1982	62 FR 42575 (8/7/1997)
insulin suspension protamine zinc purified beef	Protamine Zinc Insulin	N017928	pre-1982	61 FR 40649 (8/5/1996)
insulin suspension isophane beef/pork	NPH Iletin I	N017936	pre-1982	74 FR 6896 (2/11/2009)
insulin suspension isophane purified beef	NPH Iletin II	N018479	pre-1982	74 FR 6896 (2/11/2009)
insulin suspension isophane purified pork	NPH Iletin II	N018345	pre-1982	74 FR 6896 (2/11/2009)
insulin suspension protamine zinc beef/pork	Protamine Zinc and Iletin I	N017932	pre-1982	74 FR 6896 (2/11/2009)
insulin suspension protamine zinc purified beef	Protamine, Zinc and Iletin II	N018476	pre-1982	74 FR 6896 (2/11/2009)
insulin suspension protamine zinc purified pork	Protamine, Zinc, and Iletin II	N018346	pre-1982	74 FR 6896 (2/11/2009)
insulin zinc suspension beef	Lente Insulin	N017998	pre-1982	62 FR 42575 (8/7/1997)
insulin zinc suspension extended recombinant human	Humulin U 40 and Humulin U 100	N019571	06/10/1987	76 FR 33310 (6/8/2011)
insulin zinc suspension prompt purified pork	Semilente	N018382	pre-1982	61 FR 40649 (8/5/1996)
insulin zinc suspension purified beef	Ultralente	N018385	pre-1982	61 FR 40649 (8/5/1996)
insulin zinc suspension recombinant human	Humulin L	N019377	09/30/1985	76 FR 33310 (6/8/2011)
insulin zinc suspension semisynthetic purified human	Novolin L	N018777	08/30/1983	61 FR 40649 (8/5/1996)

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insulin zinc suspension purified beef	Lente Iletin II	N018477	pre-1982	74 FR 6896 (2/11/2009)
insulin zinc suspension purified pork	Lente Iletin II	N018347	pre-1982	74 FR 6896 (2/11/2009)
insulin zinc suspension recombinant human	Novolin L	N019965	06/25/1991	74 FR 6896 (2/11/2009)
lepirudin	Refludan	N020807	03/06/1998	83 FR 7738 (2/22/2018)
lutropin alfa	Luveris	N021322	10/8/2014	81 FR 21558 (4/12/2016)
menotropins (FSH;LH)	Menotropins	A073598	01/30/1997	83 FR 27784 (6/14/2018)
menotropins (FSH;LH)	Menotropins	A073599	01/30/1997	83 FR 27784 (6/14/2018)
pancrelipase (amylase, lipase, protease)	Ultresa	N022222	03/01/2012	84 FR 31872 (7/3/2019)
somatrem	Protropin	N019107	10/17/1985	71 FR 34940 (6/16/2006)
somatropin	Asellacrin	N017726	pre-1982	67 FR 63107 (10/10/2002)
somatropin	Crescormon	N017992	pre-1982	68 FR 49481 (8/18/2003)
somatropin	Valtropin	N021905	04/19/2007	84 FR 12262 (4/1/2019)
somatropin	Norditropin	N019721	05/08/1995	74 FR 23407 (5/19/2009)
somatropin	Nutropin Depot	N021075	12/22/1999	72 FR 62858 (11/7/2007)
sutilains	Travase	N012828	pre-1982	78 FR 43210 (7/19/13)
technetium Tc 99m albumin aggregated kit	AN-MAA	N017792	pre-1982	62 FR 50387 (9/25/1997)
technetium Tc 99m albumin aggregated kit	A-N Stannous Aggregated Albumin	N017916	pre-1982	64 FR 31226 (6/10/1999)
technetium Tc-99m albumin aggregate kit	TechneScan MAA	N017842	pre-1982	74 FR 23407 (5/19/2009)
technetium Tc-99m albumin aggregated	Tc 99m-Lungaggregate	N017848	pre-1982	72 FR 62858 (11/7/2007)
technetium Tc-99m albumin aggregated kit	Lungaggregate Reagent	N017838	pre-1982	72 FR 62858 (11/7/2007)
technetium Tc-99m albumin kit	Technetium Tc-99m HSA	N017775	pre-1982	68 FR 49481 (8/18/2003)
technetium Tc-99m albumin kit	Technetium Tc 99m MAA	N017773	pre-1982	70 FR 10651 (3/4/2005)

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technetium Tc-99m albumin microspheres kit	Instant Microspheres	N017832	pre-1982	55 FR 47807 (9/15/1990)
thyroglobulin	Proloid	N002245	pre-1982	58 FR 12042 (3/2/1993)
thyroglobulin	Thyroglobulin	A080151	pre-1982	66 FR 43017 (8/16/2001)
thyrotropin	Thytropar	N008682	pre-1982	67 FR 63107 (10/10/2002)
urofollitropin	Fertinex and Metrodin	N019415	08/23/1996	82 FR 28322 (6/21/2017)