

List of Biologics Approved via 505

1997 - Present

<u>Active Ingredient</u>	<u>Approval Year</u>	<u>Therapeutic Area</u>
teduglutide (rDNA origin)	2012	Gastrointestinal Disorders
taliglucerase alfa	2012	Metabolic Diseases
velaglucerase alfa	2010	Metabolic Diseases
liraglutide (rDNA origin)	2010	Endocrine Disorders
somatropin (rDNA origin)	2007	Endocrine Disorders
somatropin (rDNA origin)	2006	Endocrine Disorders
mecasermin rinfabate (rDNA origin)	2005	Endocrine Disorders
hyaluronidase human	2005	Pharmaceutical Aids
hyaluronidase	2005	Pharmaceutical Aids
insulin detemir	2005	Endocrine Disorders
mecasermin (rDNA origin)	2005	Endocrine Disorders
insulin detemir (rDNA origin)	2005	Endocrine Disorders
hyaluronidase	2004	Pharmaceutical Aids
lutropin alfa	2004	Endocrine Disorders
follitropin alfa	2004	Disorders of Sexual Function, Breast and Reproduction
hyaluronidase	2004	Pharmaceutical Aids
insulin glulisine (rDNA origin)	2004	Endocrine Disorders
follitropin alfa	2004	Disorders of Sexual Function, Breast and Reproduction
follitropin beta	2004	Disorders of Sexual Function, Breast and Reproduction
somatropin (rDNA origin)	2003	Gastrointestinal Disorders
pegvisomant	2003	Endocrine Disorders
teriparatide (rDNA origin)	2002	Musculoskeletal and Connective Tissue Disorders
nesiritide	2001	Cardiovascular Disorders
choriogonadotropin alfa	2000	Disorders of Sexual Function, Breast and Reproduction
somatropin (rDNA origin)	2000	Endocrine Disorders
insulin aspart (rDNA origin)	2000	Endocrine Disorders
gemtuzumab ozogamicin	2000	Cancer
insulin glargine (rDNA)	2000	Endocrine Disorders
insulin lispro (rDNA origin) protamine; insulin lispro (rDNA origin)	1999	Endocrine Disorders
insulin lispro (rDNA origin) protamine; insulin lispro (rDNA origin)	1999	Endocrine Disorders
thyrotropin alfa	1998	Cancer
rDNA Origin	1998	Endocrine Disorders
glucagon (rDNA origin)	1998	Endocrine Disorders
lepirudin (rDNA)	1998	Hematologic Diseases
follitropin alfa/beta	1997	Disorders of Sexual Function, Breast and Reproduction

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Approved for external use

Note: all drug and biological approvals are publically available at Drugs@FDA (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>)