



# APPROVED DRUG PRODUCTS

WITH

THERAPEUTIC  
EQUIVALENCE  
EVALUATIONS

31<sup>st</sup> EDITION

THE PRODUCTS IN THIS LIST HAVE BEEN APPROVED UNDER  
SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH  
OFFICE OF PHARMACEUTICAL SCIENCE  
OFFICE OF GENERIC DRUGS

2011

**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

The products in this list have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This volume is current through December 31, 2010.

**31<sup>st</sup> EDITION**



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**FOOD AND DRUG ADMINISTRATION  
 CENTER FOR DRUG EVALUATION AND RESEARCH  
 APPROVED DRUG PRODUCTS  
 with  
 Therapeutic Equivalence Evaluations**

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**PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST**

See report footnote for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>IMATINIB MESYLATE - GLEEVEC</u>						
N021588 001	5521184	Jan 04, 2015	DS DP		I-583	Dec 19, 2011
	5521184*PED	Jul 04, 2015			ODE	Oct 19, 2013
	6894051	May 23, 2019	DS DP	U-649	ODE	Oct 19, 2013
	6894051*PED	Nov 23, 2019			ODE	Oct 19, 2013
	6958335	Dec 19, 2021		U-791	ODE	Oct 19, 2013
	6958335*PED	Jun 19, 2022			ODE	Oct 19, 2013
	7544799	Jan 16, 2019	DS DP		ODE	Oct 19, 2013
	7544799*PED	Jul 16, 2019				
<u>IMATINIB MESYLATE - GLEEVEC</u>						
N021588 002	5521184	Jan 04, 2015			I-583	Dec 19, 2011
	5521184*PED	Jul 04, 2015			ODE	Oct 19, 2013
	6894051	May 23, 2019	DS DP	U-649	ODE	Oct 19, 2013
	6894051*PED	Nov 23, 2019			ODE	Oct 19, 2013
	6958335	Dec 19, 2021		U-791	ODE	Oct 19, 2013
	6958335*PED	Jun 19, 2022			ODE	Oct 19, 2013
	7544799	Jan 16, 2019	DS DP		ODE	Oct 19, 2013
	7544799*PED	Jul 16, 2019				
<u>IMIGLUCERASE - CEREZYME</u>						
N020367 001	5549892	Aug 27, 2013		U-252		
<u>IMIGLUCERASE - CEREZYME</u>						
N020367 002	5549892	Aug 27, 2013		U-252		
<u>IMIQUIMOD - ALDARA</u>						
N020723 001	5238944	Aug 24, 2010				
	5238944*PED	Feb 24, 2011				
	7696159	Apr 01, 2024	DS	U-1048		
	7696159	Apr 01, 2024	DS	U-1047		
	7696159*PED	Oct 01, 2024				
<u>IMIQUIMOD - IMIQUIMOD</u>						
A078548 001					PC	Aug 24, 2010
<u>IMIQUIMOD - ZYCLARA</u>						
N022483 001					NP	Mar 25, 2013
<u>INDINAVIR SULFATE - CRIXIVAN</u>						
N020685 001	5413999	May 09, 2012		U-132		
	6645961	Mar 04, 2018	DP			
	6689761	Feb 10, 2021		U-554		
<u>INDINAVIR SULFATE - CRIXIVAN</u>						
N020685 003	5413999	May 09, 2012		U-132		
	6645961	Mar 04, 2018	DP			
	6689761	Feb 10, 2021		U-554		
<u>INDINAVIR SULFATE - CRIXIVAN</u>						
N020685 005	5413999	May 09, 2012		U-132		
	6645961	Mar 04, 2018	DP			
	6689761	Feb 10, 2021		U-554		
<u>INDINAVIR SULFATE - CRIXIVAN</u>						
N020685 006	5413999	May 09, 2012		U-132		
	6645961	Mar 04, 2018	DP			
	6689761	Feb 10, 2021		U-554		
<u>INSULIN ASPART PROTAMINE RECOMBINANT; INSULIN ASPART RECOMBINANT - NOVLOG MIX 50/50</u>						
N021810 001	5547930	Sep 28, 2013	DS DP			
	5618913	Jun 07, 2014	DS DP			
	5618913*PED	Dec 07, 2014				
	5834422	Sep 28, 2013	DP	U-471		
	5840680	Sep 28, 2013	DS DP	U-471		
	5866538	Jun 20, 2017	DP			
	5866538*PED	Dec 20, 2017				

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<u>INSULIN ASPART PROTAMINE RECOMBINANT; INSULIN ASPART RECOMBINANT - NOVOLOG MIX 70/30</u>						
N021172 001	5547930	Sep 28, 2013	DS DP			
	5618913	Jun 07, 2014	DS DP			
	5618913*PED	Dec 07, 2014				
	5834422	Sep 28, 2013	DP	U-471		
	5840680	Sep 28, 2013	DS DP	U-471		
	5866538	Jun 19, 2017	DP			
<u>INSULIN ASPART RECOMBINANT - NOVOLOG</u>						
N020986 001	5618913	Jun 07, 2014	DS DP		D-112	Mar 14, 2011
	5618913*PED	Dec 07, 2014				
	5866538	Jun 20, 2017				
	5866538*PED	Dec 20, 2017				
<u>INSULIN DETEMIR RECOMBINANT - LEVEMIR</u>						
N021536 001	5750497	May 16, 2019	DS DP	U-668		
	5866538	Jun 20, 2017	DP			
	6011007	Feb 02, 2014	DS DP	U-668		
	6869930	Feb 02, 2014	DS DP	U-668		
<u>INSULIN GLARGINE RECOMBINANT - LANTUS</u>						
N021081 001	5656722	Aug 12, 2014	DS DP	U-948		
	5656722*PED	Feb 12, 2015				
	7476652	Jul 23, 2023	DP			
	7476652*PED	Jan 23, 2024				
	7713930	Jun 13, 2023	DP			
	7713930*PED	Dec 13, 2023				
<u>INSULIN GLULISINE RECOMBINANT - APIDRA</u>						
N021629 001	6221633	Jun 18, 2018	DS DP	U-471	NPP	Oct 24, 2011
	6960561	Jan 25, 2023	DP	U-471		
	7452860	Mar 22, 2022	DP			
	7696162	Mar 22, 2022	DP	U-471		
<u>INSULIN GLULISINE RECOMBINANT - APIDRA</u>						
N021629 002	6221633	Jun 18, 2018	DS DP	U-471	NPP	Oct 24, 2011
	6960561	Jan 25, 2023	DP	U-471		
	7452860	Mar 22, 2022	DP			
	7696162	Mar 22, 2022	DP	U-471		
<u>INSULIN GLULISINE RECOMBINANT - APIDRA SOLOSTAR</u>						
N021629 003	6221633	Jun 18, 2018	DS DP	U-471	NPP	Oct 24, 2011
	6960561	Jan 25, 2023	DP	U-471		
	7452860	Mar 22, 2022	DP			
	7696162	Mar 22, 2022	DP	U-471		
<u>INSULIN LISPRO PROTAMINE RECOMBINANT; INSULIN LISPRO RECOMBINANT - HUMALOG MIX 50/50</u>						
N021018 001	5461031	Jun 26, 2014				
	5474978	Jun 16, 2014				
	5514646	May 07, 2013				
	5747642	Jun 16, 2014				
<u>INSULIN LISPRO PROTAMINE RECOMBINANT; INSULIN LISPRO RECOMBINANT - HUMALOG MIX 75/25</u>						
N021017 001	5461031	Jun 16, 2014				
	5474978	Jun 16, 2014				
	5514646	May 07, 2013				
	5747642	Jun 16, 2014				
<u>INSULIN LISPRO RECOMBINANT - HUMALOG</u>						
N020563 001	5474978	Jun 16, 2014		U-534		
	5514646	May 07, 2013		U-534		
<u>INSULIN LISPRO RECOMBINANT - HUMALOG PEN</u>						
N020563 002	5474978	Jun 16, 2014		U-534		
	5514646	May 07, 2013		U-534		